Supreme Court, U.S.
FILED
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OFFICE OF THE CLERK

No. 14-1520

In the Supreme Court of the United States

STRYKER CORPORATION, ET AL., PETITIONERS

v.

ZIMMER, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

JOINT APPENDIX

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PETITION FOR A WRIT OF CERTIORARI FILED: JUNE 22, 2015
CERTIORARI GRANTED: OCTOBER 19, 2015

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 13-1668

Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation,
Plaintiffs-Appellees

v.

Zimmer, Inc., and Zimmer Surgical, Inc.,
Defendants-Appellants

Zimmer Orthopaedic Surgical Products,
Defendant.

Filed: September 23, 2013

Docket Entries

DATE	DOCKET NUMBER	PROCEEDINGS
09/23/2013	1	Appeal docketed. Received: 09/19/2013. [105516]
		* * * * *
01/22/2014	19	BRIEF FILED for Appellants Zimmer Surgical, Inc. and Zimmer, Inc. [18]. Title: Brief for Defendants-Appellants Zimmer, Inc. and Zimmer Surgical, Inc., [Non-Confidential version only]. Number of Pages: 71. Service: 01/21/2014 by email.. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 01/29/2014. Appellees Stryker Corporation, Stryker Puerto Rico, Ltd. and Stryker Sales Corporation brief is due 03/06/2014. [131330]
		* * * * *
3/19/2014	24	BRIEF FILED for Appellees Stryker Corporation, Stryker Puerto Rico, Ltd. and Stryker Sales Corporation [23]. Title: Brief of Appellees, [Non-Confidential version only]. Number of Pages: 89. Service:

DATE	DOCKET NUMBER	PROCEEDINGS
		03/19/2014 by email. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 03/25/2014. Appellants Zimmer Surgical, Inc. and Zimmer, Inc. reply brief is due 04/07/2014. [142829]
		* * * * *
04/28/2014	29	BRIEF FILED for Appellants Zimmer Surgical, Inc. and Zimmer, Inc. [28]. Title: Reply Brief for Appellant, Zimmer, Inc. and Zimmer Surgical, Inc., [Non-Confidential version only]. Number of Pages: 37. Service: 04/28/2014 by email.. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 05/05/2014. Appendix is due 05/08/2014. [151420]
		* * * * *
05/05/2014	32	Citation of Supplemental Authority pursuant to Fed. R. App. P. 28(j) for Appellees Stryker Corporation, Stryker Puerto

DATE	DOCKET NUMBER	PROCEEDINGS
		Rico, Ltd. and Stryker Sales Corporation. Service: 05/05/2014 by email. [152387]
		* * * * *
05/12/2014	39	RESPONSE of Appellants Zimmer Surgical, Inc. and Zimmer, Inc. to the supplemental authority [32] filed by Appellees Stryker Corporation, Stryker Sales Corporation and Stryker Puerto Rico, Ltd. in 13-1668. Service: 05/12/2014 by email. [153791]
		* * * * *
05/14/2014	43	APPENDIX FILED for Zimmer Surgical, Inc. and Zimmer, Inc. [42], [41]. Title: Joint Appendix (3 Volumes), [Confidential and Non-Confidential versions]. Number of Pages: 530. Service: 05/14/2014 by email.. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. (The conf. version of this appendix has been replaced. See entry #46) [156312]
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
05/23/2014	46	APPENDIX FILED for Zimmer Surgical, Inc. and Zimmer, Inc. [45]. Title: Joint Appendix (3 Volumes), [Confidential Only version]. Number of Pages: 1302. Service: 05/23/2014 by email.. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 06/02/2014. [157276]
		* * * * *
05/30/2014	48	MOTION of Appellees Stryker Corporation, Stryker Puerto Rico, Ltd. and Stryker Sales Corporation to file a supplemental brief. Response/Opposition is due 06/12/2014 [Consent: opposed]. Service: 05/30/2014 by email. [158064]
		* * * * *
06/18/2014	52	RESPONSE of Appellants Zimmer Surgical, Inc. and Zimmer, Inc. to the motion to file supplemental brief [48] filed by Appellees Stryker Corporation, Stryker Sales Corporation and Stryker Puerto Rico, Ltd.

DATE	DOCKET NUMBER	PROCEEDINGS
		in 13-1668. Service: 06/18/2014 by email. [162257]
06/25/2014	53	REPLY of Appellees Stryker Corporation, Stryker Puerto Rico, Ltd. and Stryker Sales Corporation to response filed by Appellants in 13-1668 , Doc. No [52]. Service: 06/25/2014 by email. [163548]
06/30/2014	54	ORDER filed denying [48] motion to file supplemental brief filed by Stryker Corporation, Stryker Sales Corporation and Stryker Puerto Rico, Ltd. without prejudice to the merits panel assigned to hear this case requesting supplemental briefing if appropriate.; and granting motion to extend time to file a response [49] filed by Appellants Zimmer, Inc. and Zimmer Surgical, Inc. Service: 06/30/2014 by clerk. [164333]
		* * * * *
09/08/2014	61	Submitted after ORAL ARGUMENT by Mr. Donald Robert Dunner for Zimmer, Inc. and Zimmer Surgical, Inc. and Miss Sharon Hwang for Stryker Corporation, Stryker Sales Corpo-

DATE	DOCKET NUMBER	PROCEEDINGS
		ration and Stryker Puerto Rico, Ltd.. Panel: Judge: Prost , Judge: Newman , Judge: Hughes. [180631]
		* * * * *
12/19/2014	66	OPINION and JUDGMENT filed. The judgment or decision is: affirmed-in=part, reversed-in-part, vacated-in-part, and remanded. (Precedential Opinion). (For the Court: Prost,Chief Judge; Newman,Circuit Judge and Hughes,Circuit Judge). [205222] Withdrawn pursuant to the court's order. See Doc. No. [84]
		* * * * *
01/20/2015	72	Petition for en banc rehearing filed by Appellees Stryker Corporation, Stryker Puerto Rico, Ltd. and Stryker Sales Corporation. Service: 01/20/2015 by email. [210990]
		* * * * *
01/22/2015	74	The court invites a response from Appellants Zimmer Surgical, Inc. and Zimmer, Inc. to the petition for en banc rehearing

DATE	DOCKET NUMBER	PROCEEDINGS
		filed by Appellees in 13-1668.. [211789]
		* * * * *
02/05/2015	76	RESPONSE of Appellants Zimmer Surgical, Inc. and Zimmer, Inc. to the petition for en banc rehearing [72] filed by Appellees Stryker Corporation, Stryker Sales Corporation and Stryker Puerto Rico, Ltd. in 13-1668. Service: 02/05/2015 by email. [215450]
02/10/2015	77	MOTION of Appellees Stryker Corporation, Stryker Puerto Rico, Ltd. and Stryker Sales Corporation for leave to file a response/reply to [76] response. Response/Opposition is due 02/23/2015 [Consent: opposed]. Service: 02/10/2015 by email. [216443]
02/10/2015	78	REPLY of Appellees Stryker Corporation, Stryker Puerto Rico, Ltd. and Stryker Sales Corporation to response filed by Appellants in 13-1668 , Doc. No [76]. Service: 02/10/2015 by email. [216444]

DATE	DOCKET NUMBER	PROCEEDINGS

* * * * *

02/18/2015	81	ORDER filed granting motion to file a response/reply [77] filed by Appellees Stryker Corporation, Stryker Sales Corporation and Stryker Puerto Rico, Ltd.. By: Merits Panel (Per Curiam). Service as of this date by Clerk of Court. [218113]
02/19/2015	82	RESPONSE of Appellants Zimmer Surgical, Inc. and Zimmer, Inc. to the motion to file a response/reply [77] filed by Appellees Stryker Corporation, Stryker Sales Corporation and Stryker Puerto Rico, Ltd. in 13-1668. Service: 02/19/2015 by email. [218357]
02/23/2015	83	CORRECTED ORDER: correcting court order [81]; reason(s): Opposition filed. Service as of this date by Clerk of Court.
03/23/2015	84	ORDER filed granting panel rehearing for limited purpose; withdrawing the Precedential Opinion [66]. By: Merits Panel (Per Curiam). Service as of this date by Clerk of Court. [226332]

DATE	DOCKET NUMBER	PROCEEDINGS
03/23/2015	85	OPINION and JUDGMENT filed. The judgment or decision is: Affirmed-in-Part, Reversed-in-Part, Vacated-in-Part, Remanded. (Precedential Opinion). (For the Court: Prost,Chief Judge; Newman,Circuit Judge and Hughes,Circuit Judge). [226338]
03/23/2015	86	ORDER filed denying [72] petition for en banc rehearing filed by Stryker Corporation, Stryker Sales Corporation and Stryker Puerto Rico, Ltd. By: En Banc (Per Curiam). Service as of this date by Clerk of Court. [226342]
03/24/2015	87	ERRATA to the Precedential Opinion Doc No.: [85]. Service as of this date by Clerk of Court. [226762]
		* * * * *
06/24/2015	89	Petition for writ of Certiorari filed on 06/22/2015 in the Supreme Court of the United States. Supreme Court #: 14-1520, Stryker Corporation v. Inc. Zimmer. [251992]

DATE	DOCKET NUMBER	PROCEEDINGS
		* * * * *
10/19/2015	93	The petition for writ of certiorari, [14-1520], filed on 06/22/2015, was Granted on 10/19/2015. The petition for a writ of certiorari in no. 14-1513 is granted limited to Question 1 presented by the petition. The cases are consolidated and a total of one hour is allotted for oral argument. [282062]--[Edited 10/26/2015 by SJ to correct docket text]

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

No. 10-cv-01223

Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation,
Plaintiffs

v.

Zimmer, Inc., Zimmer Orthopaedic Surgical Products, and Zimmer Surgical, Inc.,
Defendants

Filed: December 10, 2010

Docket Entries

DATE	DOCKET NUMBER	PROCEEDINGS
		* * * * *
11/07/2011	66	BRIEF by counter-defendants Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation, plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation *"Plaintiff Stryker's Opening Markman Brief"* (Gass, David) (Entered: 11/07/2011)
		* * * * *
12/05/2011	76	MARKMAN BRIEF on claim construction issues submitted for filing by defendants Zimmer Inc., Zimmer Orthopaedic Surgical Products, counter-claimants Zimmer Inc., Zimmer Orthopaedic Surgical Products *Defendant Zimmer's Responsive Markman Brief - Public Redacted Version* (Brausa, Adam) (Entered: 12/05/2011)
		* * * * *
12/19/2011	86	MARKMAN BRIEF on claim construction issues submitted for filing by plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation *"Plaintiff Stryker's Reply Markman Brief"* (Portinga, D.)

DATE	DOCKET NUMBER	PROCEEDINGS
		(Entered: 12/19/2011)
		* * * * *
02/01/2012	106	CLAIM CONSTRUCTION MEMORANDUM OPINION AND ORDER; signed by Judge Robert J. Jonker (Judge Robert J. Jonker, mil) (Entered: 02/01/2012)
		* * * * *
07/31/2012	156	MOTION for partial summary judgment of infringement by counter-defendants Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation, plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation; (Portinga, D.) Modified text on 8/11/2012 (gjf). (Entered: 07/31/2012)
		* * * * *
07/31/2012	165	MOTION for summary judgment *of Non-Infringement of U.S. Patent No. 6,022,329* by defendants Zimmer Inc., Zimmer Orthopaedic Surgical Products, counter-claimants Zimmer Inc., Zimmer Orthopaedic Surgical Products; (Hales, Bryan) (En-

DATE	DOCKET NUMBER	PROCEEDINGS
		tered: 07/31/2012)
		* * * * *
07/31/2012	170	MOTION for summary judgment of *Invalidity of Claims 45 and 50-52 of U.S. Patent No. 6,179,807* by defendants Zimmer Inc., Zimmer Orthopaedic Surgical Products, counter-claimants Zimmer Inc., Zimmer Orthopaedic Surgical Products; (Hales, Bryan) (Entered: 07/31/2012)
		* * * * *
08/28/2012	211	RESPONSE in opposition to MOTION for summary judgment *of Non-Infringement of U.S. Patent No. 6,022,329* 165 filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Portinga, D.) (Entered: 08/28/2012)
		* * * * *
08/28/2012	215	RESPONSE in opposition to MOTION for summary judgment *of Invalidity of Claims 45 and 50-52 of U.S. Patent No. 6,179,807* 170 filed by Stryker Corporation, Stryker Puerto Ri-

DATE	DOCKET NUMBER	PROCEEDINGS
		co, Ltd., Stryker Sales Corporation (Portinga, D.) (Entered: 08/28/2012)
		* * * * *
08/28/2012	225	RESPONSE in opposition to MOTION for summary judgment 156 *Zimmer's Opposition to Stryker's Motion for Partial Summary Judgment of Infringement* filed by Zimmer Inc., Zimmer Orthopaedic Surgical Products (Attachments: #1 Exhibit A, #2 Exhibit B, #3 Exhibit C, #4 Exhibit C, #4 Exhibit D, #5 Exhibit E)(Hales, Bryan) (Entered: 08/28/2012)
		* * * * *
09/11/2012	231	REPLY to response to motion 156 *for partial summary judgment of infringement* filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Paul, Justin) (Entered: 09/11/2012)
09/11/2012	232	REPLY to response to motion 170 *for Summary Judgment of Invalidity of Claims 45 and 50-52 of U.S. Patent No. 6,179,807* filed by Zimmer Inc., Zimmer

DATE	DOCKET NUMBER	PROCEEDINGS
		Orthopaedic Surgical Products (Hales, Bryan) (Entered: 09/11/2012)
		* * * * *
09/11/2012	236	REPLY to response to motion 165 *for Summary Judgment of Non-Infringement of U.S. Patent No. 6,022,329* filed by Zimmer Inc., Zimmer Orthopaedic Surgical Products (Attachments: # 1 Exhibit 1 in Support of Reply Brief, # 2 Exhibit 2 in Support of Reply Brief, # 3 Exhibit 3 in Support of Reply Brief, # 4 Exhibit 4 in Support of Reply Brief)(Hales, Bryan) (Entered: 09/11/2012)
		* * * * *
11/29/2012	247	ORDER granting in part and denying in part 156 motion for summary judgment; signed by Judge Robert J. Jonker (Judge Robert J. Jonker, ymc) Modified text on 12/12/2012; see 254 for revision (kvt). (Entered: 11/29/2012)
11/29/2012	248	ORDER denying 165 motion for summary judgment; signed by Judge Robert J. Jonker (Judge

DATE	DOCKET NUMBER	PROCEEDINGS
		Robert J. Jonker, ymc) (Entered: 11/29/2012)
11/29/2012	249	ORDER denying 170 motion for summary judgment; signed by Judge Robert J. Jonker (Judge Robert J. Jonker, ymc) (Entered: 11/29/2012)
		* * * * *
12/07/2012	254	ORDER granting motion to clarify 252 re 247; the Court GRANTS Plaintiff's Motion to Clarify. The Court's earlier Order 247 is REVISED to read as proposed in the Motion to Clarify, and in particular to GRANT Plaintiff's Motion for Summary Judgment of infringement on Claim 10 of the '383 Patent, as well as the other Claims originally included in the Order 247 ; signed by Judge Robert J. Jonker (Judge Robert J. Jonker, ymc) (Entered: 12/07/2012)
		* * * * *
02/01/2013	377	NOTICE: Court's Final Version of the Jury Instructions and Verdict Form; signed by Judge Robert J. Jonker (Attachments: #1 Attachment Jury Instruc-

DATE	DOCKET NUMBER	PROCEEDINGS
		tions, #2 Attachment Verdict Form) (Judge Robert J. Jonker, ymc) (Entered: 02/01/2013)
		* * * * *
02/05/2013	381	JURY VERDICT (gjf) (Entered: 02/05/2013)
		* * * * *
03/22/2013	396	MOTION for permanent injunction *or, in the Alternative, an Ongoing Royalty* by counter-defendants Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation, plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation; (Portinga, D.) (Entered: 03/22/2013)
		* * * * *
03/22/2013	401	MOTION for judgment as a matter of law *Zimmer's Post-Trial Motion No. 3 for Judgment as a Matter of Law of Invalidity of Claim 2 of U.S. Patent No. 6,022,329, Or in the Alternative, For a New Trial* by defendants Zimmer Orthopaedic Surgical Products, Zimmer, Inc., counter-claimants Zimmer

DATE	DOCKET NUMBER	PROCEEDINGS
		Orthopaedic Surgical Products, Zimmer, Inc.; (Hales, Bryan) (Entered: 03/22/2013)
		* * * * *
03/22/2013	405	MOTION for order *for Enhanced Damages* by counter-defendants Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation, plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation; (Portinga, D.) (Entered: 03/22/2013)
		* * * * *
03/22/2013	410	MOTION for order *for a Finding of Exceptional Case and for an Award of Attorneys' Fees* by counter-defendants Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation, plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation; (Portinga, D.) (Entered: 03/22/2013)
		* * * * *
03/22/2013	425	MOTION for judgment as a matter of law *Zimmer's Post-*

DATE	DOCKET NUMBER	PROCEEDINGS
		Trial Motion No. 4 for Judgment as a Matter of Law of Non-Infringement of Claim 2 of U.S. Patent No. 6,022,329, Or in the Alternative, For a New Trial by defendants Zimmer Orthopaedic Surgical Products, Zimmer, Inc., counter-claimants, Zimmer Orthopaedic Surgical Products, Zimmer, Inc.; (Hales, Bryan) (Entered: 03/22/2013)
		* * * * *
03/22/2013	435	MOTION for new trial *Zimmer's Post-Trial Motion No. 9 for a New Trial* by defendants Zimmer Orthopaedic Surgical Products, Zimmer, Inc., counter-claimants Zimmer Orthopaedic Surgical Products, Zimmer, Inc.; (Hales, Bryan) (Entered: 03/22/2013)
		* * * * *
03/22/2013	438	MOTION for judgment as a matter of law *Zimmer's Post-Trial Motion No. 2 for Judgment as a Matter of Law of Invalidity of the Asserted Claims of U.S. Patent No. 7,144,383, Or in the Alternative, For a New*

DATE	DOCKET NUMBER	PROCEEDINGS
		Trial by defendants Zimmer Orthopaedic Surgical Products, Zimmer, Inc., counter-claimants Zimmer Orthopaedic Surgical Products, Zimmer, Inc.; (Hales, Bryan) (Entered: 03/22/2013)
		* * * * *
03/22/2013	442	MOTION for judgment as a matter of law *Zimmer's Post-Trial Motion No. 1 for Judgment as a Matter of Law of Invalidity of Claims 45 and 50-52 of U.S. Patent No. 6,179,807, Or in the Alternative, For a New Trial* by defendants Zimmer Orthopaedic Surgical Products, Zimmer, Inc., counter-claimants Zimmer Orthopaedic Surgical Products, Zimmer, Inc.; (Hales, Bryan) (Entered: 03/22/2013)
		* * * * *
03/22/2013	447	MOTION for judgment as a matter of law *Zimmer's Post-Trial Motion No. 5 for Judgment as a Matter of Law of No Willful Infringement* by defendants Zimmer Orthopaedic Surgical Products, Zimmer, Inc., counter-claimants Zimmer Orthopaedic Surgical Products,

DATE	DOCKET NUMBER	PROCEEDINGS
		Zimmer, Inc.; (Hales, Bryan) (Entered: 03/22/2013)
		* * * * *
04/19/2013	460	RESPONSE in opposition to Zimmer's Post-Trial MOTION No. 9 for a New Trial 435 filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Volger, Gregory) Modified text on 4/22/2013 (gjf). (Entered: 04/19/2013)
		* * * * *
04/19/2013	475	RESPONSE in opposition to Zimmer's Post-Trial MOTION No. 3 for Judgment as a Matter of Law of Invalidity of Claim 2 of U.S. Patent No. 6,022,329, Or in the Alternative, For a New Trial 401 filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 PTX 1, # 2 PTX 13, # 3 PTX 18, # 4 PTX 21, # 5 PTX 23)(Vogler, Gregory) Modified text on 4/22/2013 (gjf). (Entered: 04/19/2013)
		* * * * *
04/19/2013	482	RESPONSE in opposition to Zimmer's Post-Trial MOTION

DATE	DOCKET NUMBER	PROCEEDINGS
		No. 1 for Judgment as a Matter of Law of Invalidity of Claims 45 and 50-52 of U.S. Patent No. 6,179,807, Or in the Alternative, For a New Trial 442 filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 PTX 2, # 2 PTX 9, # 3 PTX 13, # 4 PTX 21, # 5 PTX 23)(Vogler, Gregory) Modified text on 4/22/2013 (gjf). (Entered: 04/19/2013)
		* * * * *
04/19/2013	486	RESPONSE in opposition to Zimmer's Post-Trial MOTION No. 2 for Judgment as a Matter of Law of Invalidity of the Asserted Claims of U.S. Patent No. 7,144,383, Or in the Alternative, For a New Trial 438 filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 PTX 1, # 2 PTX 3, # 3 PTX 13, # 4 PTX 14, # 5 PTX 18)(Vogler, Gregory) Modified text on 4/22/2013 (gjf). (Entered: 04/19/2013)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
04/19/2013	491	RESPONSE in opposition to Zimmer's MOTION No. 4 for Judgment as a Matter of Law of Non-Infringement of Claim 2 of U.S. Patent No. 6,022,329, Or in the Alternative, For a New Trial 425 filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 PTX 1, # 2 PTX 8, # 3 PTX 9, # 4 PTX 15 - Part 1, # 5 PTX 15 - Part 2)(Vogler, Gregory) Modified text on 4/22/2013 (gjf). (Entered: 04/19/2013)
		* * * * *
04/19/2013	495	RESPONSE in opposition to MOTION for permanent injunction *or, in the Alternative, an Ongoing Royalty* 396 filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit 205, # 2 Exhibit AGA, # 3 Exhibit AGB)(Hales, Bryan) (Entered: 04/19/2013)
04/19/2013	496	RESPONSE in opposition to Zimmer's MOTION No. 5 for Judgment as a Matter of Law of No Willful Infringement 447 filed by Stryker Corporation,

DATE	DOCKET NUMBER	PROCEEDINGS
		Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 PTX 1, # 2 PTX 2, # 3 PTX 3, # 4 PTX 13)(Vogler, Gregory) Modified text on 4/22/2013 (gjf). (Entered: 04/19/2013)
		* * * * *
04/19/2013	501	RESPONSE in opposition to MOTION for order *for Enhanced Damages* 405 *Under 35 U.S.C. § 284* filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit AGD, # 2 Exhibit 1, # 3 Exhibit 2, # 4 Exhibit 3, # 5 Exhibit 14)(Hales, Bryan) (Entered: 04/19/2013)
		* * * * *
04/19/2013	505	RESPONSE in opposition to MOTION for order *for a Finding of Exceptional Case and for an Award of Attorneys' Fees* 410 *Under 35 U.S.C § 285* filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit AGD, # 2 Exhibit AE, # 3 Exhibit 15, # 4 Exhibit 9A, # 5 Exhibit QF)(Hales, Bryan) (Entered:

DATE	DOCKET NUMBER	PROCEEDINGS
		04/19/2013)
		* * * * *
05/03/2013	519	REPLY to response to motion 401 *Zimmer's Reply in Support of Its Post-Trial Motion No. 3 for Judgment as a Matter of Law of Invalidity of Claim 2 of U.S. Patent No. 6,022,329, Or in the Alternative, For a New Trial* filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit AEG-12) (Hales, Bryan) (Entered: 05/03/2013)
05/03/2013	520	REPLY to response to motion 396 *for a permanent injunction or, in the alternative, an ongoing royalty* filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 Exhibit PTX 2, # 2 Exhibit PTX 23, # 3 Exhibit PTX 41, # 4 Exhibit PTX 42 (labeled as PTX 41), # 5 Exhibit PTX 61)(Vogler, Gregory) Modified text on 5/6/2013 (gjf). (Entered: 05/03/2013)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
05/03/2013	522	REPLY to response to motion 425 *Zimmer's Reply in Support of Its Post-Trial Motion No. 4 for Judgment as a Matter of Law of Non-Infringement of Claim 2 of U.S. Patent No. 6,022,329, Or in the Alternative, For a New Trial* filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit 1, # 2 Exhibit AE, # 3 Exhibit QB, Ex. E)(Hales, Bryan) (Entered: 05/03/2013)
05/03/2013	523	REPLY to response to motion 438 *Zimmer's Reply in Support of Its Post-Trial Motion No. 2 for Judgment as a Matter of Law of Invalidity of the Asserted Claims of U.S. Patent No. 7,144,383, Or in the Alternative, For a New Trial* filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit 3, # 2 Exhibit IB, # 3 Exhibit T, # 4 Exhibit Y, # 5 Exhibit QF)(Hales, Bryan) (Entered: 05/03/2013)
		* * * * *
05/03/2013	525	REPLY to response to motion 442 *Zimmer's Reply in Support*

DATE	DOCKET NUMBER	PROCEEDINGS
		of Its Post-Trial Motion No. 1 for Judgment as a Matter of Law of Invalidity of Claims 45 and 50-52 of U.S. Patent No. 6,179,807, Or in the Alternative, For a New Trial filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit 9, # 2 Exhibit 2, # 3 Exhibit ACM, # 4 Exhibit ADC, # 5 Exhibit PW)(Hales, Bryan) (Entered: 05/03/2013)
		* * * * *
05/03/2013	527	REPLY to response to motion 435 *Zimmer's Reply in Support of Its Post-Trial Motion No. 9 for a New Trial* filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit AGV)(Hales, Bryan) (Entered: 05/03/2013)
05/03/2013	528	REPLY to response to motion 405 *for enhanced damages* filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 Exhibit PTX 14, # 2 Exhibit PTX 15 - Part 1, # 3 Exhibit PTX 15 - Part 2, # 4 Exhibit PTX 23, # 5 Exhibit DTX

DATE	DOCKET NUMBER	PROCEEDINGS
		KS)(Vogler, Gregory) (Entered: 05/03/2013)
05/03/2013	529	REPLY to response to motion 410 *for a finding of an exceptional case and an award of attorneys' fees* filed by Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 Exhibit PTX 15 - Part 1, # 2 Exhibit PTX 15 - Part 2, # 3 Exhibit PTX 23, # 4 Exhibit DTX KS)(Vogler, Gregory) (Entered: 05/03/2013)
05/03/2013	530	REPLY to response to motion 447 *Zimmer's Reply in Support of Its Post-Trial Motion No. 5 for Judgment as a Matter of Law of No Willful Infringement* filed by Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Attachments: # 1 Exhibit 15, # 2 Exhibit AE, # 3 Exhibit QF)(Hales, Bryan) (Entered: 05/03/2013)
		* * * * *
08/07/2013	537	ORDER denying 369 motion for judgment as a matter of law; granting 396 motion for permanent injunction; granting 399

DATE	DOCKET NUMBER	PROCEEDINGS
		motion for order; denying 401 motion for judgment as a matter of law; granting 405 motion for order, granting 410 motion for order; granting 414 motion for order; denying 418 motion for entry of judgment ; denying 425 motion for judgment as a matter of law; denying 430 motion for judgment as a matter of law; denying 435 motion for new trial; denying 438 motion for judgment as a matter of law; denying 442 motion for judgment as a matter of law; denying 447 motion for judgment as a matter of law; denying 453 motion for judgment as a matter of law; granting 534 motion to strike ; signed by Judge Robert J. Jonker (Judge Robert J. Jonker, ymc) (Entered: 08/07/2013)
		* * * * *
09/05/2013	546	FINAL JUDGMENT and PERMANENT INJUNCTION in favor of Stryker Corporation, Stryker Puerto Rico, Ltd, and Stryker Sales Corporation against Zimmer Inc. and Zimmer Surgical, Inc.; signed by

DATE	DOCKET NUMBER	PROCEEDINGS
		Judge Robert J. Jonker (Judge Robert J. Jonker, ymc) (Entered: 09/05/2013)
		* * * * *
09/19/2013	555	NOTICE OF APPEAL to the Federal Circuit Court of Appeals re 546 by defendants Zimmer Orthopaedic Surgical Products, Zimmer, Inc., counter-claimants Zimmer Orthopaedic Surgical Products, Zimmer, Inc. (Hales, Bryan) (Entered: 09/19/2013)
		* * * * *
09/19/2013	559	MOTION for attorney fees */Petition for an Award of Attorneys' Fees Under 35 USC 285 and Expert Fees* by plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation; (Vogler, Gregory) (Entered: 09/19/2013)
		* * * * *
12/19/2014	569	JUDGMENT of Federal Circuit Court of Appeals re appeal 555 *AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED (mandate to issue)*

DATE	DOCKET NUMBER	PROCEEDINGS
		(kvt) (Entered: 01/27/2015)
		* * * * *
03/23/2015	574	REVISED OPINION and ORDER of Federal Circuit Court of Appeals re appeal 555 *affirmed-in-part, reversed-in-part, vacated-in-part, and remanded; mandate to issue* (pjw) Modified text on 3/24/2015 (pjw). Modified text on 3/25/2015 (cmi). (Entered: 03/24/2015)
03/24/2015	575	ERRATA *from the United States Court of Appeals for the Federal Circuit regarding Opinion and Order 574* (pjw) Modified document link on 3/25/2015 (pjw). (Entered: 03/25/2015)
		* * * * *
05/18/2015	580	ORDER granting PROPOSED AMENDED FINAL JUDGMENT AND PERMANENT INJUNCTION 579; signed by Judge Robert J. Jonker (Judge Robert J. Jonker, ymc) (Entered: 05/18/2015)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
10/21/2015	591	NOTICE of *Supreme Court Order Granting Certiorari* by plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., Stryker Sales Corporation (Attachments: # 1 Exhibit A) (Hwang, Sharon) (Entered: 10/21/2015)

* * * * *

The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extension.

J. Todd Dickinson

Commissioner of Patents and Trademarks

Attest M. Peterson

NOTICE

If the application for this patent was filed on or after December 12, 1980, maintenance fees are due three years and six months, seven years and six months, and eleven years and six months after the date of this grant, or within a grace period of six months thereafter upon payment of a surcharge as provided by law. The amount, number and timing of the maintenance fees required may be changed by law or regulation. Unless payment of the applicable maintenance fee is received in the Patent and Trademark Office on or before the date the fee is due or within a grace period of six months thereafter, the patent will expire as of the end of such grace period.

US006022329A

United States Patent [19]

Arnett et al.

[11] Patent Number: 6,022,329

[45] Date of Patent: *Feb. 8, 2000

[54] IRRIGATION HANDPIECE WITH BUILT IN PULSING PUMP

[75] Inventors: Jeffrey D. Arnett, Kalamazoo; Nicholas V. Gulsby, Portage; David R. Grellar, Battle Creek; Ruth A. Hibbins, Delton; James L. Hovis, Kalamazoo, all of Mich.

[73] Assignee: Stryker Corporation, Kalamazoo, Mich.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: 08/909,687

[22] Filed: Jan. 30, 1998

Related U.S. Application Data

[63] Continuation of application No. 08/399,133, Mar. 17, 1995, Pat. No. 5,718,684, which is a continuation of application No. 08/049,344, Apr. 19, 1988, Pat. No. 5,470,305.

[51] Int. Cl.[7] A61M 3/00

[52] U.S. Cl. 604/159; 239/526; 239/379; 604/35; 604/153; 604/43; 604/161

[58] Field of Search ..... 604/154, 155, 604/180, 164, 302, 143, 185; 604/33, 35, 39, 43, 155; 128/DIG. 10, DIG. 12; 433/80, 74/325, 327, 328, 409; 239/522, 332.2, 291.1; 239/525, 526, 373; 222/333

[56] References Cited

U.S. PATENT DOCUMENTS

589,239	11/1897	Gustafson .
908,466	4/1908	Schroeder .
736,503	8/1903	Weiser .
792,309	3/1905	Bellinger .
1,317,891	10/1919	Aaron .
1,505,239	8/1924	Pfirrmann .
1,520,807	3/1925	Schulte .
1,846,506	2/1932	Hamberg .
2,012,888	9/1935	Lowry .
2,112,029	3/1938	Lloyd .
2,139,433	12/1938	Bellinger .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0 278 906	8/1988	European Pat. Off.
1 325 930	8/1963	France .
24 16 089	4/1975	Germany .
WO94/15820	8/1994	Japan .
1 264 138	2/1972	United Kingdom .
2 085 434A	4/1982	United Kingdom .
WO81/00794	3/1981	WIPO .
WO81/02235	8/1981	WIPO .
WO85/05982	9/1985	WIPO .
WO88/08947	4/1988	WIPO .
WO89/12830	8/1989	WIPO .
WO90/01508	12/1990	WIPO .
WO90/17771	9/1990	WIPO .
WO94/13351	6/1994	WIPO .
WO94/27771	12/1994	WIPO .

OTHER PUBLICATIONS

Pulsavac, Operations Manual Pulsatile Lavage Debridement System (15 sheets) Jan. 1983 Stryker Laboratories, Inc. Dover, Ohio 44622.

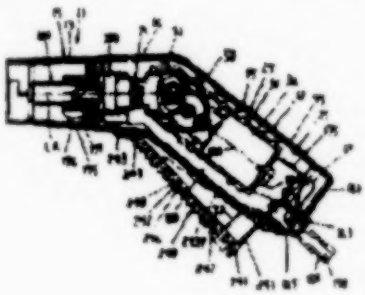
(List continued on next page.)

Primary Examiner—Denise D. DeMille
Attorney, Agent, or Firm—Flynn, Thiel, Boutell & Tanis, P.C.

[57] ABSTRACT

A pulsed irrigation handpiece comprises a pulsed irrigation liquid outlet for applying liquid pulses to a surgical site, a pump unit reciprocatingly drivable for pumping pulses of irrigation liquid through the outlet, an electric powered drive unit for reciprocatingly driving the pump unit, and a housing containing the pump and drive units. A irrigation inlet hose leads from the pump unit out of the handpiece housing and is connectable to a source irrigation liquid source. An irrigation inlet hose adjacent the source and thereof and electric conductors extending along the irrigation inlet hose transfer electric power from the supply unit to the drive unit in the handpiece. Removable tips are alternatively removably attachable to the irrigation liquid outlet adjacent the front end of the handpiece.

10 Claims, 17 Drawing Sheets



U.S. PATENT DOCUMENTS

2,197,995	4/1940	Crowley
2,243,299	5/1941	Brown
2,494,088	1/1950	Dalby
2,531,399	11/1950	Sokol
3,595,494	3/1952	Schroeder
3,634,885	4/1953	Heath
3,682,489	12/1972	Riley
2,684,049	7/1954	Hollis
2,727,678	12/1955	Henderson
2,753,113	2/1956	Kalbach
2,781,134	2/1957	Meredith
2,802,666	8/1957	Thorne
2,847,087	8/1958	Fox
2,874,886	2/1959	Bond
2,908,371	10/1959	Hearne
2,993,654	7/1961	Nestor
3,004,288	9/1961	Pendleton
3,014,627	12/1961	Hines et al.
3,039,372	6/1962	Peck
3,066,663	7/1962	Anderson et al.
3,048,121	8/1962	Sweeney
3,078,089	12/1962	Dark
3,135,259	6/1964	Brown
3,227,138	1/1966	Montagh
3,237,388	3/1966	Stuart
3,263,643	8/1966	Carpenter
3,270,571	1/1967	Smith
3,316,845	5/1967	Schneider
3,373,557	11/1967	Kaye et al.
3,399,599	12/1967	Johnson et al.
3,393,671	7/1968	Montagh
3,416,387	12/1968	VanDenkel et al.
3,425,410	2/1969	Dunsmuir
3,438,743	2/1969	Clawson et al.
3,448,746	6/1969	Schmidt
3,452,746	7/1969	Blankenship
3,464,121	12/1969	Quarton
3,508,548	6/1970	Rogers et al.
3,515,130	6/1970	Teague
3,561,433	2/1971	Kovach
3,601,464	8/1971	Brown
3,675,556	09/1971	Bohannon
3,675,607	1/1972	Opsvig
3,653,377	4/1972	Rebold
3,702,141	11/1972	Whitehouse
3,713,339	1/1973	Runnells
3,731,641	5/1973	Lloyd et al.
3,731,876	5/1973	Rebold
3,762,641	10/1973	Lloyd et al.
3,765,602	10/1973	Lowenstein et al.
3,768,472	10/1973	Richards et al.
3,771,522	11/1973	Wagner et al.
3,784,235	1/1974	Kessler et al.
3,790,031	2/1974	Nixon
3,857,345	12/1974	Bonah
3,864,383	1/1975	Kovach
3,883,074	5/1975	Lambert
3,888,743	5/1975	Wagner
3,940,753	4/1976	Dunkleman
3,949,934	4/1976	Rosenberg
3,982,549	9/1976	Ross
3,988,566	10/1976	Wilmoth
3,993,884	11/1976	Nemeth
4,007,750	2/1977	Ross et al.
4,018,695	4/1977	Yang
4,020,998	5/1977	Troughton
4,044,342	12/1977	Tuttle
4,111,391	9/1978	Pfeifle
4,123,594	10/1978	Chesebro et al.
4,205,876	6/1980	Humphrey et al.
4,213,476	7/1980	Armstrong
4,248,569	2/1981	Lewis
4,259,879	2/1981	Tassel
4,257,416	3/1981	Prager
4,257,547	3/1981	Wennemann
4,253,726	6/1981	Sokol
4,256,025	6/1981	Phillips et al.
4,270,078	5/1981	Smith
4,282,847	8/1981	De Toni
4,288,454	9/1981	Binder
4,294,251	10/1981	Cannavedi et al.
4,308,748	11/1981	Kendry
4,313,099	2/1982	Smith
4,334,540	2/1982	Phillips et al.
4,348,869	9/1982	Mayfield
4,358,477	9/1982	Bond
4,395,289	7/1983	McCullough
4,434,010	1/1984	McCullough
4,434,035	1/1984	Hanson
4,438,345	1/1984	Burbach et al.
4,438,348	1/1984	Peyton et al.
4,438,495	3/1984	McCullough
4,440,819	3/1984	Walling
4,449,827	5/1984	Kuhlmann
4,451,599	5/1984	Mahon
4,468,258	7/1984	Bonneville et al.
4,468,225	8/1984	Mayfield
4,472,120	9/1984	McCullough
4,483,345	11/1984	Chow et al.
4,484,909	11/1984	Leroy
4,489,720	12/1984	Rehring
4,493,684	1/1985	Wentworth
4,502,588	3/1985	Ross
4,508,532	4/1985	Brown et al.
4,509,507	4/1985	Yoho
4,512,668	4/1985	McCullough
4,515,532	5/1985	Walling
4,519,505	5/1985	Adkisson et al.
4,526,572	7/1985	Lanier et al.
4,535,773	8/1985	Yoon
4,537,182	8/1985	Glass
4,551,389	8/1985	Jain
4,552,120	11/1985	Kinsdale
4,558,457	11/1985	Williams et al.
4,561,431	12/1985	Adkisson
4,561,856	12/1985	Coulson
4,588,336	4/1986	Campbell et al.
4,593,331	6/1986	Monahan
4,598,749	6/1986	Rheng et al.
4,596,388	6/1986	Smith et al.
4,604,719	7/1986	Moll
4,604,089	8/1986	Bomengale et al.
4,634,420	1/1987	Spinosa et al.
4,636,197	4/1987	Adkisson
4,655,366	4/1987	Thistle et al.
4,660,724	4/1987	Richmond
4,665,705	4/1987	Bond
4,669,320	5/1987	Mahong
4,667,655	5/1987	Ogle et al.
4,682,643	5/1987	Chow
4,686,648	8/1987	Monhanan
4,700,580	10/1987	Bulanda et al.
4,744,878	5/1988	Mahong
4,748,970	6/1988	Mahgoun
4,784,668	8/1988	Bulanda et al.
4,788,668	8/1988	Bonanda et al.
4,795,040	10/1988	Pyatov et al.
4,799,481	1/1989	Thomas, et al.
4,817,588	4/1989	Dunn
4,872,837	10/1989	Isaacson et al.
4,890,600	1/1990	McCullough et al.
4,941,481	7/1990	McCullough et al.

4,925,450	5/1990	Inoue et al.	
4,927,340	5/1990	McCullough	
4,995,889	6/1990	Hanna	
4,941,872	7/1990	Pollis et al.	
4,957,483	9/1990	Gonzalez et al.	
4,973,302	12/1990	Pu et al.	
4,982,739	1/1991	Hausmann et al.	
5,015,235	5/1991	Landis	
5,046,486	9/1991	Chaffee et al.	
5,049,671	9/1991	Davis et al.	
5,053,008	10/1991	Bodicker	
5,098,387	3/1992	Hlavin et al.	
5,120,305	6/1992	Bontempo et al.	
5,147,323	9/1992	Lasting	
5,190,779	12/1992	Glucksberg	
5,176,627	1/1993	Kalfas et al.	
5,186,714	2/1993	Bonnebaum et al.	
5,188,591	2/1993	Dorsey, III	
5,195,959	3/1993	Smith	
5,197,649	3/1993	Bessler	
5,209,709	4/1993	Clement et al.	
5,234,409	7/1993	Bonnebaum et al.	
5,261,905	11/1993	Doresqe, III	
5,269,730	12/1993	Gaither et al.	
5,295,956	3/1994	Baker et al.	
5,308,318	5/1994	Weldon	
5,322,503	6/1994	Desai	
5,336,230	8/1994	Hollister et al.	
5,391,145	2/1995	Dorsey	
5,470,305	11/1995	Aznoni et al.	
5,484,402	1/1996	Saravia et al.	
5,544,649	8/1996	Wallstein et al.	
5,562,640	10/1996	McCabe et al.	
5,573,508	11/1996	Dorsey, III	
5,584,577	12/1996	Dorsey, III	
5,711,668	2/1998	Azzoni et al.	

OTHER PUBLICATIONS

Davol Instruction for Use, Simpulse™ Suction/Irrigator (2 sheets) Davol Inc. 800 Sockanosett Crossroad Cranston, R I 02920 Jan. 1995.

Copy of photos of Bibicon, photos of Pfizer, Valley Lambs (10 photos) Jan. 25, 1993.

Duo-™ Minimal Access Surgery System, Introducing the VAC-™ Handcontrolled Suction Irrigation Instrument. Combined Aspen Surgical Systems. Created Jul. 1992, 10M

DAVOL—Hydro-Flo™ Irrigator Bard, Davol Inc.; instruction booklet 004102-0, 9811R, Nov. 1998.

Peristalic Lavage Debridement System, brochure No. 82-010-5150-0346/2.5M CESS Zimmer Inc., Snyder Labs Inc. 1982

Suction/Irrigation Is No Longer An Issue. Hydro-Dissection System. 556529 PP 8/34 Jul. 1992. Karl Storz Lambda & Co. Tuttlingen West Germany.

A Fully Integrated Laparoscopic Irrigation and Instrumentation System, Cabot Medical, Langhorne PA Apr. 1992. 10M L/T (4 sheets)

Advances in Pulsatility, The Irrigation Pump System, Cabot Medical Langhorne, PA Apr. 1990 (3 sheets).

InteSERT™, Fluid Management System User's Manual, Smith & Nephew Dyonics Inc. copyright 1992, PN10080170

Davol, Arthro-Flo®, Instructions For Use, 020457-0 9018, C.R. Bard, Inc. Cranston RI. Jan. 1990.

Davol, Arthro-Flo High-Flo Irrigator, Bard, (IP--AF0015080 Aug. 1992 5M C.R. Bard Inc. Cranston, RI.

3M Fluid Control System, For Precise Control of all Arthroscopic Procedures, 70-2006-5458-9, 1992 3M.

Davol Simpulse-™ Suction/Irrigator, BARD, 054089-0 (2 sheets) Jan. 1985.

U.S. Patent Feb. 8, 2000 Sheet 1 of 17 6,022,329

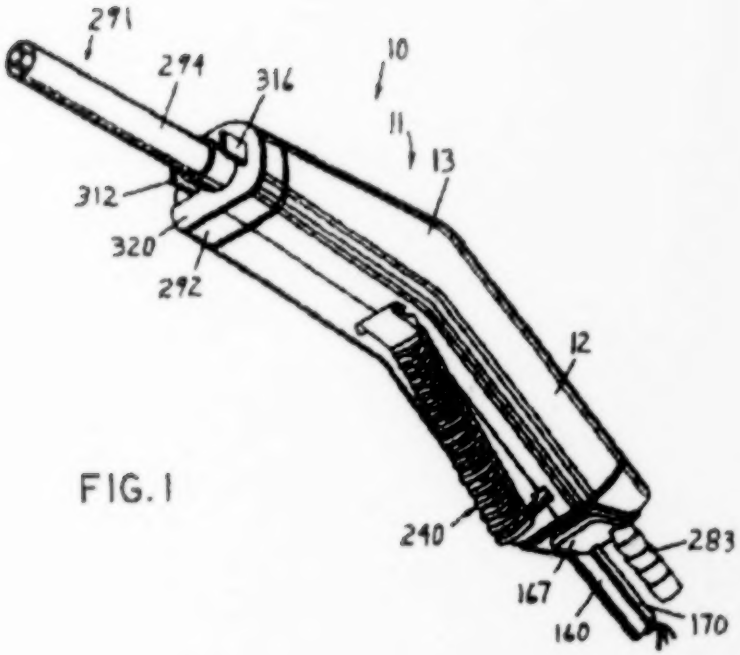


FIG. 1

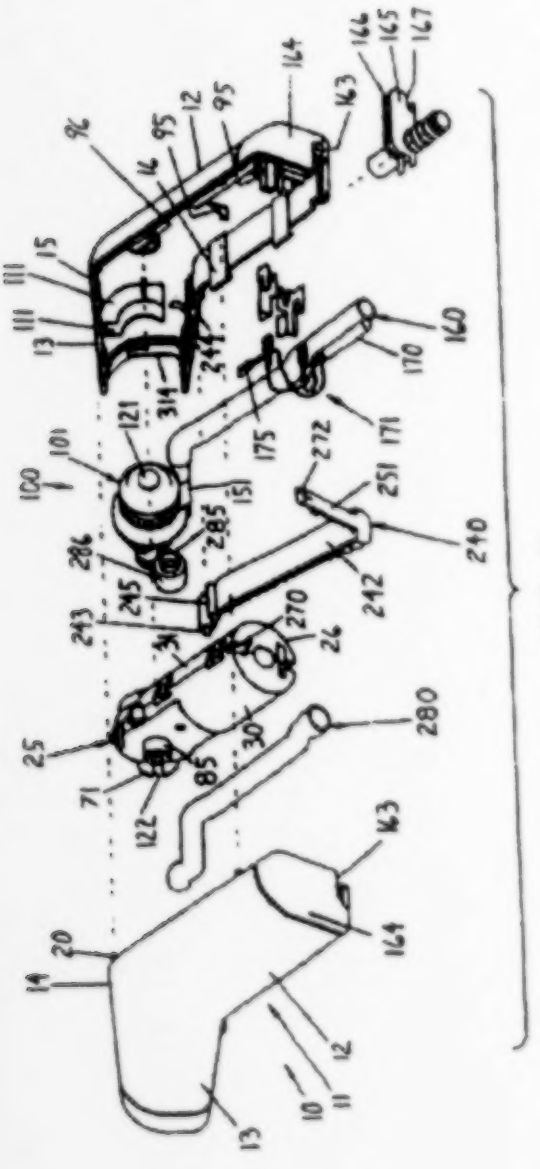

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FIG. 2

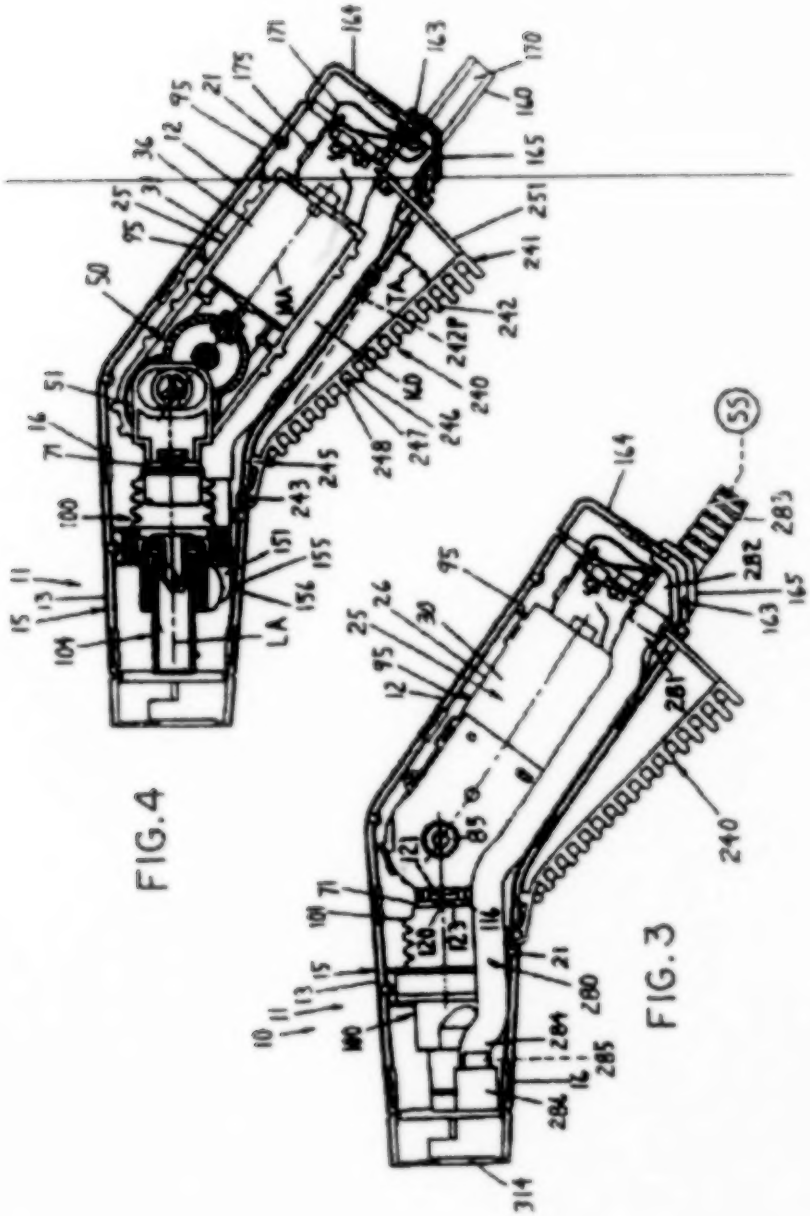
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FIG. 4

FIG. 3

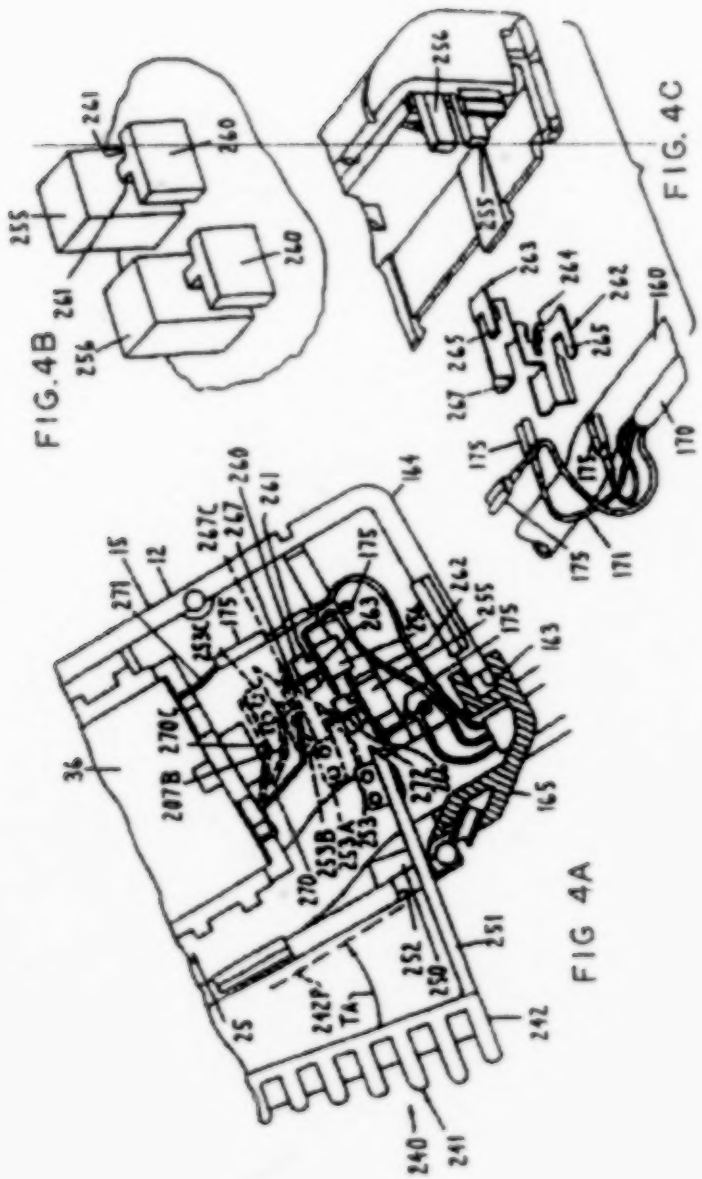
FIG. 4B
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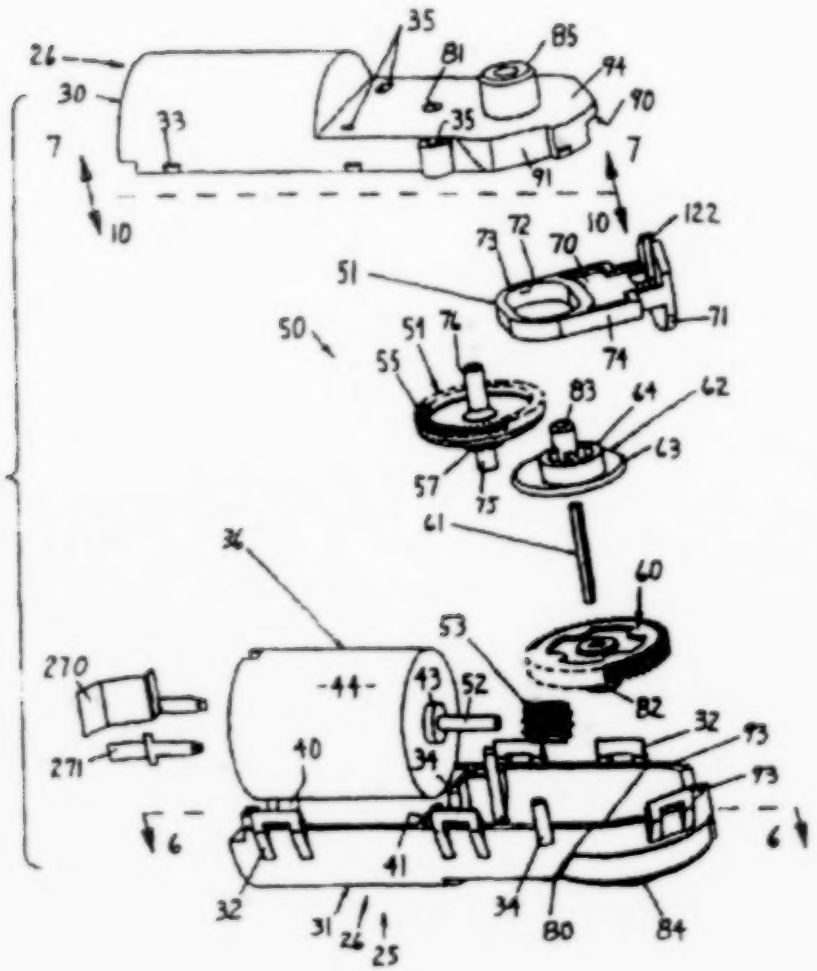
FIG 4A

FIG. 5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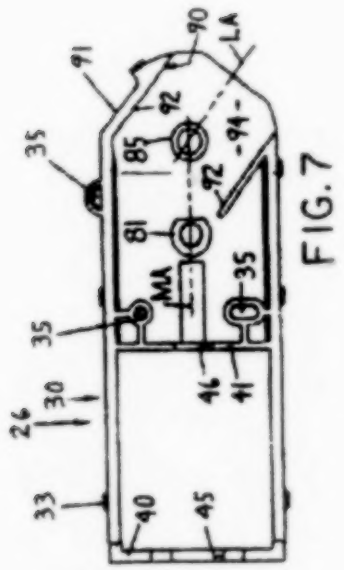


FIG. 7

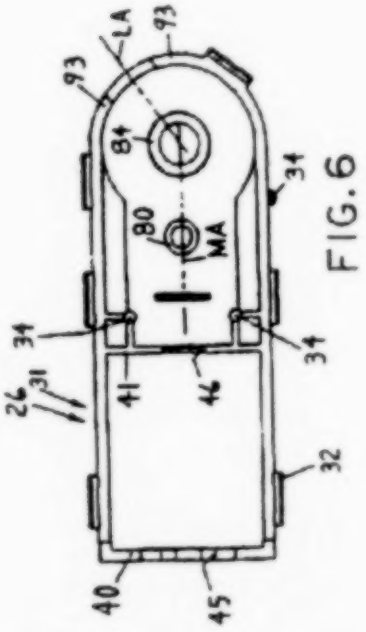


FIG. 6

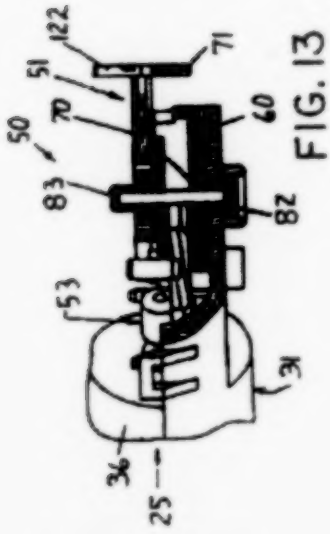


FIG. 13

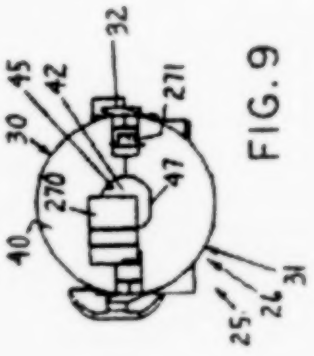
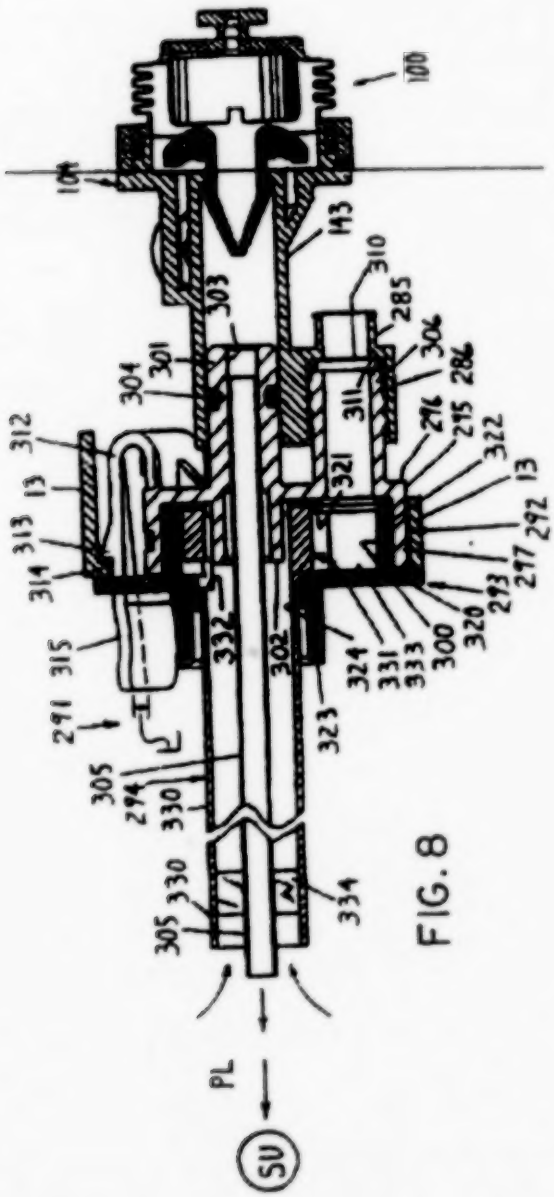


FIG. 9


100
143
310
285
303
304
301
306
286
311
216
215
322
312
13
321
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332
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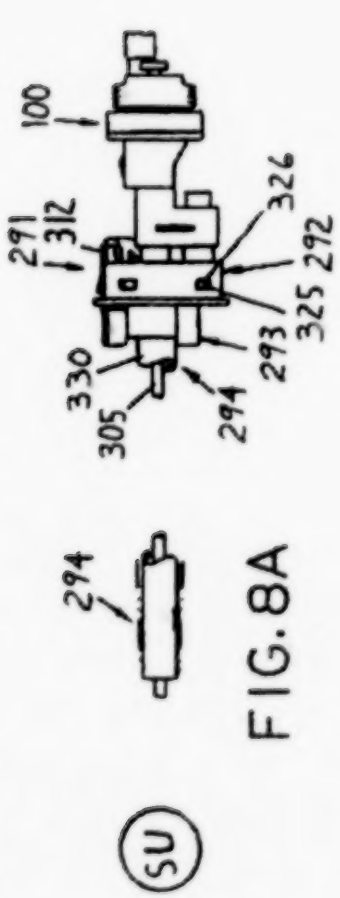
274
330
334
PL
SU

FIG. 8


100
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312
326
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293
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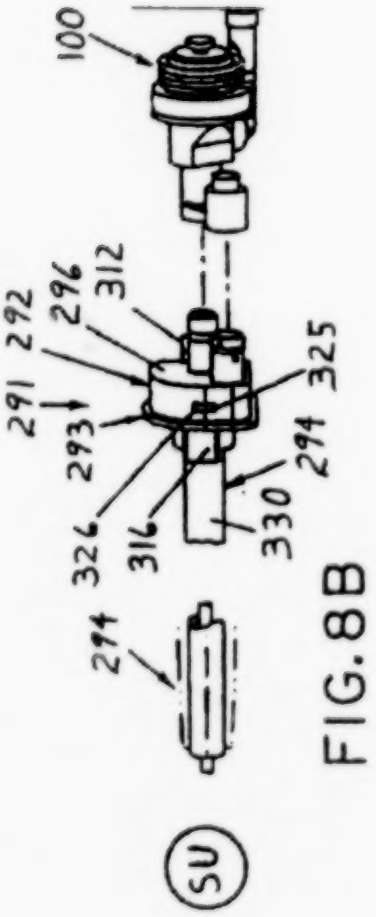
294
SU

FIG. 8A


100
291
292
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325
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326
316
330
294
SU

FIG. 8B

U.S. Patent Feb. 8, 2000 Sheet 9 of 17 6,022,329

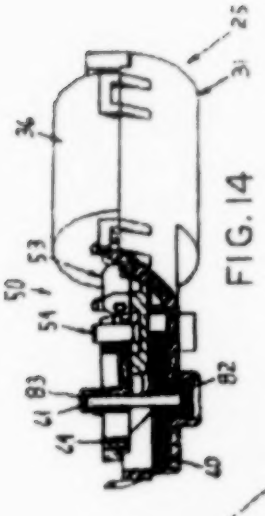


FIG. 14

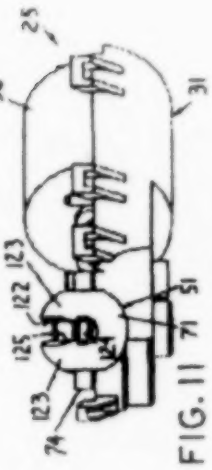


FIG. 11

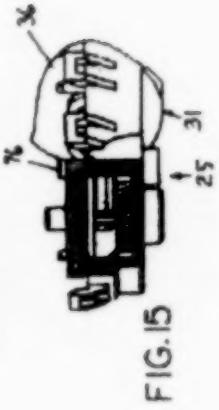


FIG. 15

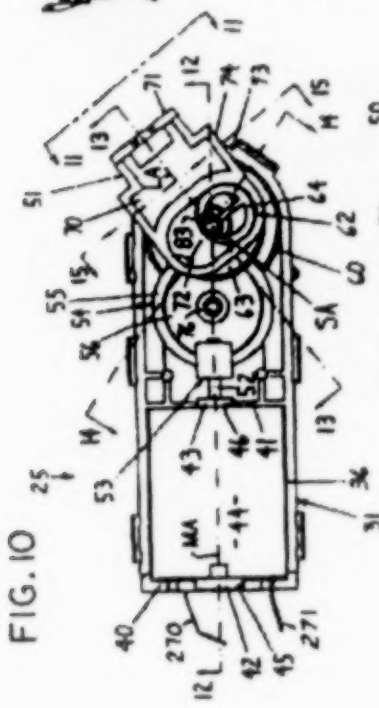


FIG. 10

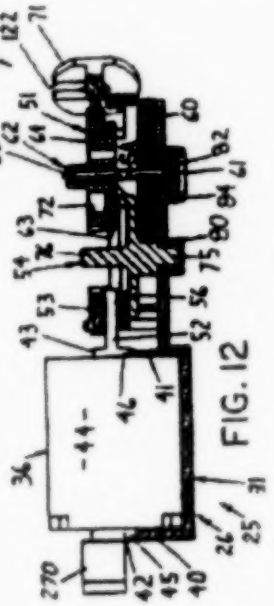
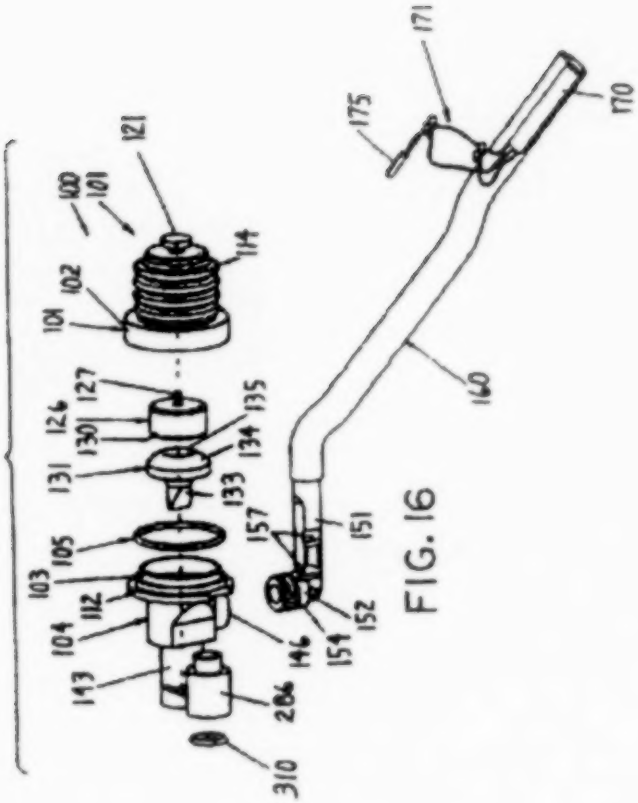


FIG. 12


171
175
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121
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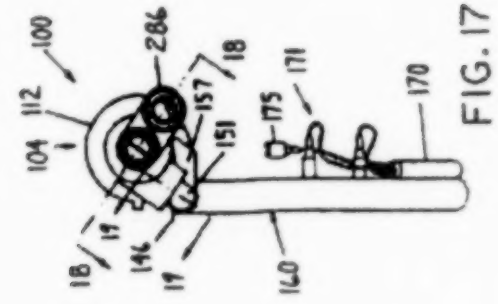
146
143
286
310

FIG. 16


100
286
18
112
157
171
104
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175
170
19
146
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140

FIG. 17

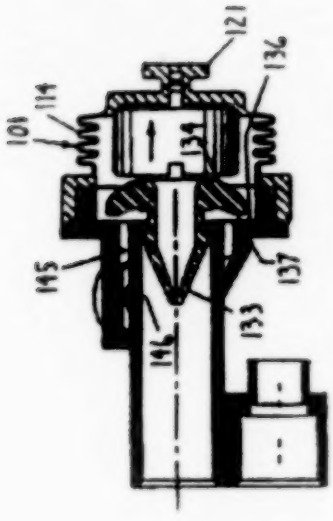

FIG. 18A

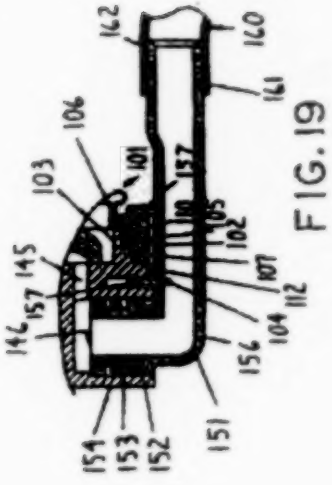

FIG. 19

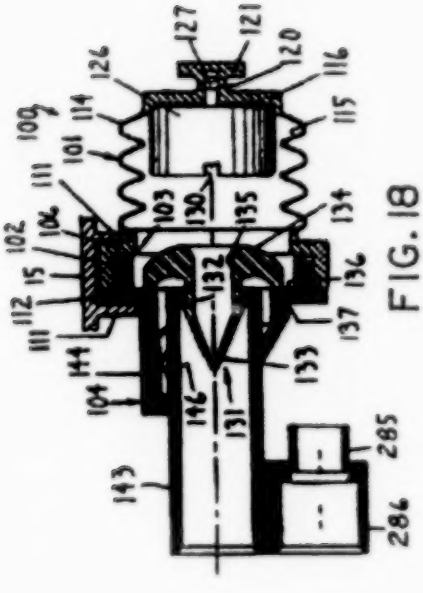

FIG. 18

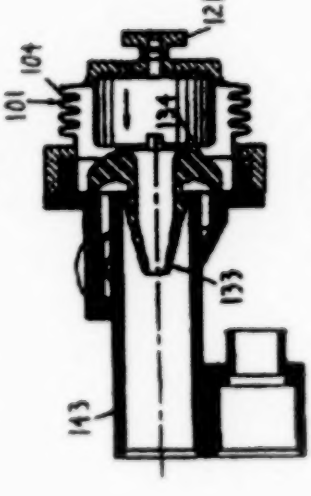

FIG. 18B

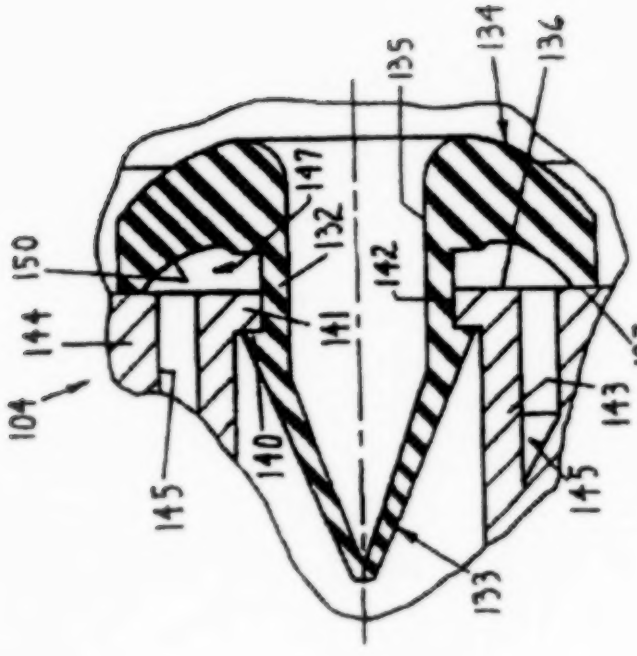

FIG. 18C

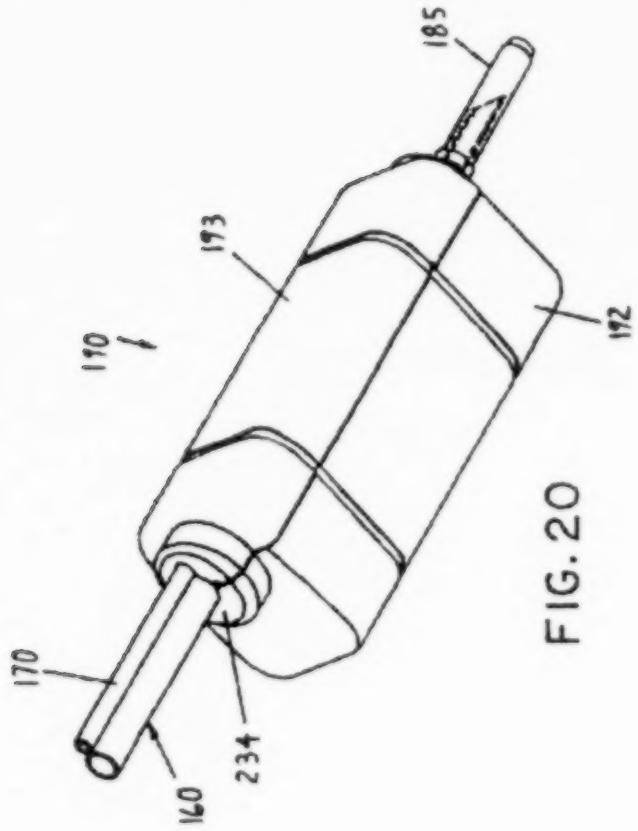

FIG. 20

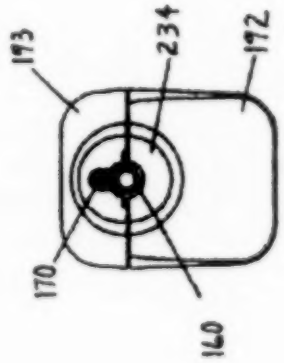

FIG. 21

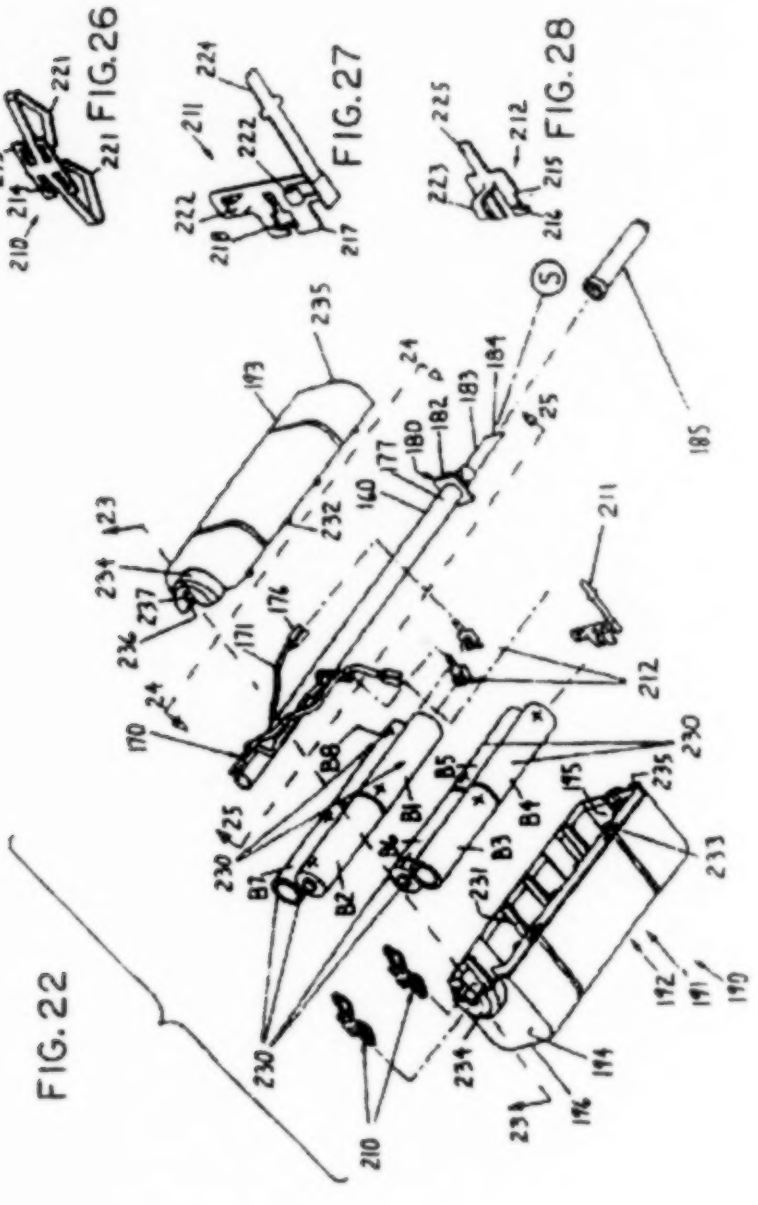
FIG.26
FIG.27
FIG.28
FIG. 22

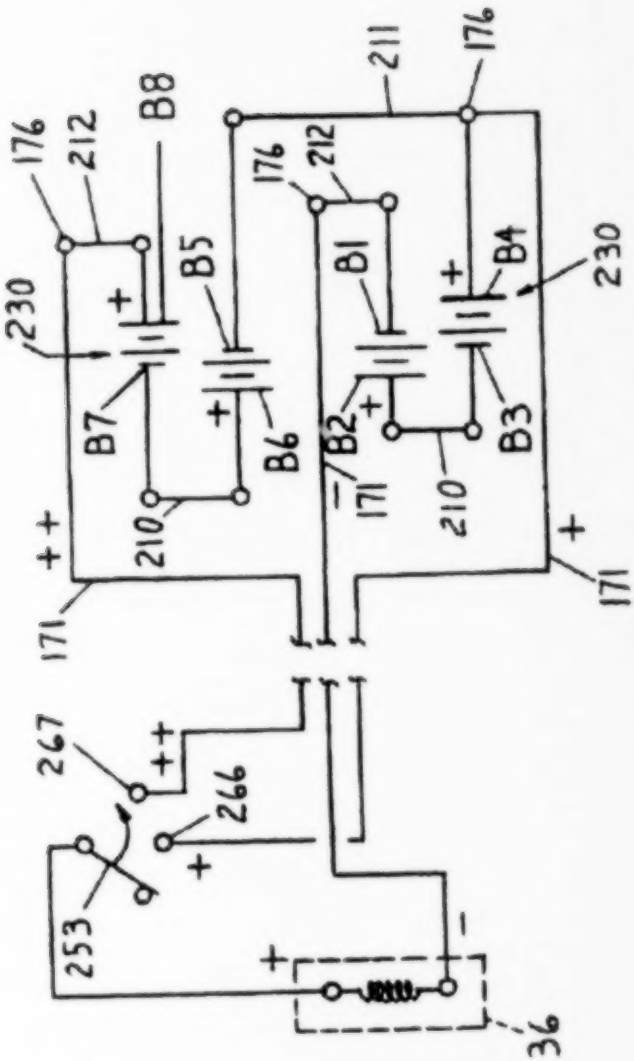
176
212
B8
B5
176
212
211
176
230
B7
B6
B2
B1
B4
B3
230
210
171
210
171
++
+
267
++
266
+
253
+
-
36

FIG. 22A

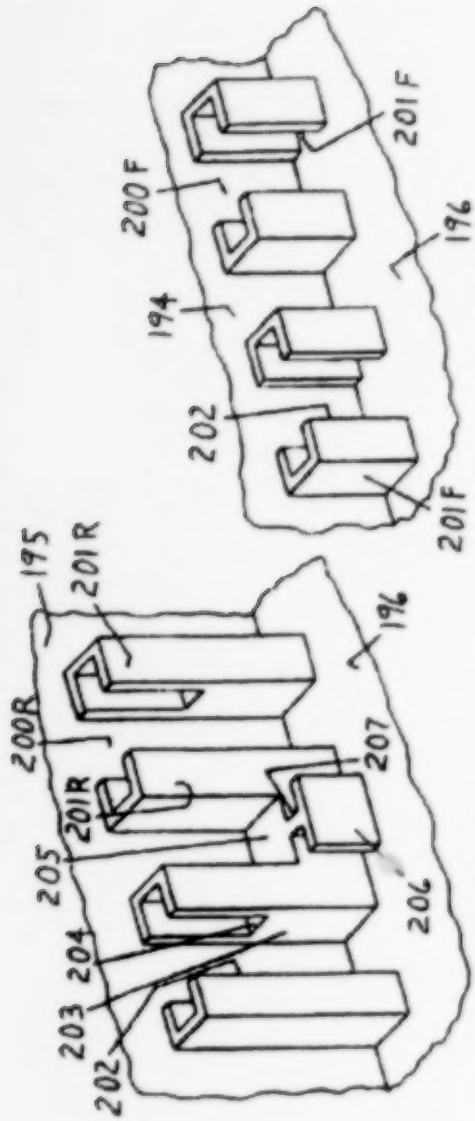

FIG. 23A

FIG. 23B

235
195
201R
230
231
-B8- +
+ -B1-
-B7- +
+ -B2-
201F
234
174
190
FIG. 24
180
184
185
183
235
201R
182
175
211
177
212
230
232
193
191
190
237
140
210
201F
234
196
192
FIG. 23
232
193
170
140
FIG. 25
180
174
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160
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161
162
151
154
FIG. 29

IRRIGATION HANDPIECE WITH BUILT IN PULSING PUMP

This is a continuation of Ser. No. 08/559,133, filed Nov. 17, 1995, now U.S. Pat. No. 5,718,668, which is a continuation of Ser. No. 08/049,144, filed Apr. 19, 1993 now U.S. Pat. No. 5,470,305.

FIELD OF THE INVENTION

This invention relates to a surgical irrigation with a built in pulsing pump.

BACKGROUND OF THE INVENTION

Grulke et al U.S. Pat. No. 5,046,486, assigned to the Assignee of the present invention, discloses a surgical pulsed irrigation handpiece which produces a pulsed irrigation liquid output capable of loosening and floating debris at a surgical site for subsequent removal (as by suction). This prior pulsed irrigation handpiece has been on the market for several years and has proved generally effective for its intended use and hence has been popular in the surgical community.

However, in a continuing effort to improve on existing devices of this general kind, the present invention has been developed. As compared to the above-mentioned prior device, a pulsed irrigation handpiece embodying the present invention is producible at lower cost, produces sharper liquid pulse transients (particularly the pulse "off" transient), requires no connection to any operating room power source (e.g. compressed air) or to an external pump, and instead is self-contained, requires only external connection to a irrigation liquid source (e.g. conventional irrigation liquid bag), provides better suction (when suction is

required), is more compact, and is conveniently shaped to be held either as a pistol or a wand (by the handle or barrel).

Other objects, purposes and advantages of the invention will be apparent to those acquainted with apparatus as general kind upon reading the following description and inspecting the accompanying drawings.

SUMMARY OF THE INVENTION

A pulsed irrigation handpiece comprises pulsed irrigation liquid outlet means for applying liquid pulses to a surgical site, pump means reciprocatingly drivable for pumping pulses of irrigation liquid through said outlet means, powered drive means for reciprocatingly driving said pump means and housing means containing said pump means and drive means.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a pictorial view of a handpiece embodying the invention.

FIG. 2 is a laterally exploded pictorial view of the FIG. 1 handpiece.

FIG. 3 is an enlarged elevational view of the FIG. 1 handpiece with the leftward housing part removed.

FIG. 4 is a view similar to FIG. 3 but with the suction hose removed, the left drive unit shell part removed and the drive unit exposed in central cross-section, such that FIG. 4 approximates a central cross-sectional view of the FIG. 1 handpiece.

FIG. 4A is an enlarged fragment of FIG. 4 detailing the rearward portion of the handle.

FIG. 4B is an enlarged fragmentary pictorial view, taken from the front, of the electrical contact support posts seen in FIG. 4A.

FIG. 4C is an enlarged fragmentary exploded pictorial view of the electrical contacts, associated with the FIG. 4B posts and associated electrical conductors from the battery supply.

FIG. 5 is an enlarged, exploded, pictorial view of the drive unit of FIG. 2.

FIG. 6 is a sectional view substantially taken on the line 6–6 of FIG. 5, and provides a top view of the bottom drive unit shell part of FIG. 5 (the rightward one of FIG. 2) with the drive components removed to show the interior configuration of that shell part.

FIG. 7 is a sectional view substantially taken on the line 7–7 of FIG. 5, and provides a view similar to FIG. 6 but showing the interior configuration of the other drive unit shell part (the upper one in FIG. 5 and leftward one in FIG. 2).

FIG. 8 is an enlarged central cross-sectional view of a tip unit usable with the handpiece of FIG. 2 and showing same installed in a pump unit shown in central cross-section substantially as in FIG. 4.

FIG. 8A is a reduced size, fragmentary, side elevational view of the apparatus of FIG. 8.

FIG. 8B is a pictorial view of the apparatus of FIG. 8A.

FIG. 9 is an end elevational view of the drive unit, taken from the right end in FIGS. 2 and 3.

FIG. 10 is a sectional view substantially taken on the line 10–10 of FIG. 5 and showing the drive unit with one shell part (the left one in FIG. 2 and top one in FIG. 5) removed to show the motor and transmission.

FIG. 11 is an elevational view of the drive train substantially taken on the line 11–11 of FIG. 10.

FIG. 12 is a central cross-sectional view substantially taken on the line 12–12 of FIG. 10.

FIG. 13 is a fragmentary cross-sectional view substantially taken on the line 13–13 of FIG. 10.

FIG. 14 is a cross-sectional view substantially taken on the line 14–14 of FIG. 10.

FIG. 15 is a sectional view substantially taken on the line 15–15 of FIG. 10.

FIG. 16 is an exploded pictorial view of the pump unit of FIG. 2 in an enlarged scale.

FIG. 17 is a front end elevational view of the pump unit of FIG. 16 taken substantially from the left side of FIGS. 2–4 and 16.

FIG. 18 is a central cross-sectional view of the pump unit of FIG. 17 taken substantially on the line 18–18 of FIG. 17.

FIG. 18A is a fragment of FIG. 18 showing the pump unit at the beginning of an intake stroke.

FIG. 18B is a fragment of FIG. 18 showing the pump nearing the end of an output pulse.

FIG. 18C is a fragmentary enlargement of FIG. 18 showing the valve member.

FIG. 19 is a fragmentary cross-sectional view showing the connection of the pump unit to the liquid supply hose.

FIG. 20 is a pictorial view of the electric power supply unit connected to the FIG. 2 handpiece.

FIG. 21 is a left end view of the FIG. 20 electric power supply unit.

FIG. 22 is an exploded pictorial view of the electric power supply unit of FIG. 20.

FIG. 22A is an electrical schematic of the FIG. 2 handpiece and FIG. 20 electric power supply unit.

FIG. 23 is a central cross-sectional view taken substantially on the line 23–23 of FIG. 22.

FIG. 23A is an enlarged fragmentary pictorial view of the support structure for battery contacts at the forward (left in FIG. 23) end of the electric power supply casing.

FIG. 23B is an enlarged pictorial view similar to FIG. 23A but showing the support structure for battery contacts at the rearward (rightward in FIG. 23) end of the power supply casing.

FIG. 24 is a sectional view substantially taken on the line 24–24 of FIG. 22 and showing the electric power supply unit with its top cover removed.

FIG. 25 is a sectional view substantially taken on the line 25–25 of FIG. 22 and showing the underside of the cover of the power supply casing.

FIGS. 26, 27 and 28 are enlarged pictorial views of battery contacts of FIG. 22.

FIG. 29 is an enlarged fragmentary pictorial view of an embodiment of the liquid supply and electric wiring harness of the apparatus of FIGS. 2 and 20 but showing a modification in the attachment of the electrical and liquid handling components.

In the following detailed discussion the terms "up", "down", "right" and "left", and variations thereon, refer to structural elements in their positions in specified drawing figures.

DETAILED DESCRIPTION

A pulsed irrigation handpiece 10 (FIGS. 1 and 2) embodying the invention comprises a hand-held housing 11 having a handle 12 and a barrel 13 which extends forward from the upper end of the handle 12 at about a 130° to 150° (here about 145°) angle thereto.

The housing 11 is hollow and, for convenience in assembling the handpiece 10, is constructed as laterally opposed concave left and right housing parts 14 and 15 (FIG. 2). The housing parts 14 and 15 are preferably molded rigid plastic elements held together rigidly by any convenient means, here comprising undercut snap fit tabs 16 protruding from the top and

bottom edges of the right housing part 15 to snap over an interior edge flange (not shown) on the top and bottom edge of the left housing part 14. If desired, precise registry together of the two housing parts can be assisted by laterally projecting pins 20 distributed along the edges of one housing part (here the left housing part 14) piloted in holes 21 (FIG. 4) in the opposed edges of the other housing part (here 15). Upon completion of assembly of the handpiece 10, the two housing parts 14 and 15 may be adhesively bonded together. The handpiece is intended to be a disposable item and therefore access to the interior of the housing for purposes of repair is not needed.

Drive Unit

The drive unit 25 (FIGS. 2-15) is self contained in its own shell 26 (FIG. 2). For convenience in assembly, the shell 26 comprises two opposed concave shell parts 30 and 31 respectively disposed to the left and right in FIG. 2. The shell parts 30 and 31 are preferably of rigid molded plastics material. When the drive unit 25 has been assembled, as in FIGS. 2 and 9, the shell parts 30 and 31 are held fixedly together by any convenient means, here by resilient snap connection of generally U-shaped clips 32, molded in spaced relation along the perimeter edge of the shell part 31 which overlap the perimeter edge of the shell part 30 and snap over tabs 33 protruding therefrom, as seen in FIGS. 5-7. Precise location of the shell parts 30 and 31 with respect to each other is assisted by locator pins 34 fixedly protruding from the shell part 31 and holes 35 in the opposed portions of the shell part 30.

A conventional DC energizable electric motor 36 (FIGS. 4 and 5) is snugly housed in the space between

the left and right (FIG. 2) shell parts 30 and 31 at the rear (left in FIGS. 5-7, 10 and 12) thereof. The motor 36 is snugly axially located between the rear end wall 40 and a transverse internal bulkhead 41 of the shell 26 (FIGS. 5-7, 10 and 12). The rear end wall 40 and bulkhead 41 have opposed parts in the left and right shell parts 30 and 31, as seen in FIGS. 6 and 7.

Rear and front bosses 42 and 43 respectively extend rearward and forward from the cylindrical casing 44 of the motor 36, as seen in FIGS. 10 and 12, and are supported in corresponding coaxial recesses 45 and 46 in the rear end wall 40 and bulkhead 41 respectively, so as to support the motor casing 44 with respect to the shell 26. A flat 47 on the rear boss 42 (FIG. 9) co-acts with a corresponding flat in the surrounding recess 45 to prevent rotation of the motor casing 44 with respect to the shell parts 30 and 31, such that the motor 36 is antirotationally fixed within the shell 26.

The drive unit 25 further includes a transmission 50 (FIG. 5) coaxial with and forward of the motor 36. The transmission includes a reciprocating link member 51 and is driven from the forward extending, rotating output shaft 52 of the motor 36. The shaft 52 extends coaxially forward through the front boss 43 (FIG. 12) of the motor 36.

The transmission 50 (FIGS. 5 and 12) includes a pinion gear 53 fixed on the motor shaft 52 for rotation thereby, and a face gear 54 which, as seen in FIG. 12, underlies the pinion gear 53. The face gear 54 has a relatively large diameter central disk 56 carrying upward facing teeth 55 engaging corresponding teeth on the pinion gear 53 for rotation thereby. The face gear

54 includes a secondary pinion gear 57 fixed coaxially beneath the disk 56, and of substantially lesser diameter, which in turn drives a relatively large diameter output gear 60.

It will be understood that the pinion gear 53, face gear 54, secondary pinion 57 and output gear 60 are all provided with a full circumferential (360°) set of teeth, so that continuous rotation of the motor shaft 52 results in continuous rotation of the output gear 60. For convenience in drawing, some or all the gear teeth are not shown in various of the drawings, the toothed meshing connection of the gears therein thus being only schematically shown. See for example FIGS. 4, 10, 12, 13 and 14.

An output shaft 61 is fixed to and coaxially upstanding from the output gear 60 (FIG. 12) and fixedly rotatably drives an eccentric member 62 (FIGS. 5, 10 and 12) spaced above the output gear 60. In this embodiment, the output shaft is of rectangular cross-section to maximize its torque transmitting capability.

The eccentric member 62 comprises a radially extending disk 63 (FIG. 5) coaxial with the output shaft 61 and fixedly surmounted by an eccentric circular cylinder 64 eccentrically rotatable with the output shaft 61.

The link member 51 is generally T-shaped, as seen in FIG. 13, having a plate-like body 70 overlying the disk 63 of the eccentric member 62 and lying at right angles to the output shaft 61, and further having a plate-like fork 71 fixed at the rightward (FIGS. 5, 10, 12 and 13) end of the plate-like body 70 and extending in a plane substantially parallel to the output shaft 61.

The plane of the plate-like fork 71 is perpendicular to the intended direction of reciprocating movement of the link member 51. The body 70, at its end portion remote from the fork 71, has an oblong through opening 72 snugly radially receiving the rotating eccentric cylinder 64 of the eccentric member 62, as seen in FIG. 10. More particularly, the length direction of the oblong opening 72 extends parallel to the plane of the fork 71 and is of sufficient length to accommodate 360° rotation of the eccentric cylinder 64 without movement of the body 70 parallel to the plane of the fork 71. On the other hand, the width of the oblong opening 72, namely in a direction perpendicular to the plane of the fork 71, corresponds substantially to the diameter of the eccentric cylinder 64, providing a sliding clearance between the body 70 and eccentric cylinder 64, so that rotation of the eccentric cylinder 64 will result in reciprocation of the link member 51 in a direction perpendicular to the plane of the fork 71.

The plate-like body 70 includes a thickened rim 73 (FIG. 5) around the oblong opening 72 and may thus be said to form a yoke for coaction with the eccentric cylinder 64. The side edges of the body 70 are preferably also thickened to form parallel longitudinal guide rails 74 (FIG. 10).

The above discussed moving elements of the transmission 50 are located and movably supported within the shell 26 as follows. The face gear 54 has coaxial downward and upward (FIGS. 5-7, 10 and 12) extending stub shafts 75 and 76 respectively rotatably supported in coaxial bearing bosses 80 and 81 respectively fixed on the opposing faces of the shell parts 31 and 30 (FIGS. 6, 7 and 12). Similarly, the output gear 60 and the eccentric member 62 have respective

downward and upward extending stub shafts 82 and 83 coaxial with the output shaft 61 and rotatably supported in respective cylindrical bearing bosses 84 and 85 in the respective shells 31 and 30 (FIGS. 5-7 and 12). The link member 51 is slidably guided for reciprocation in a notch 90 (FIGS. 5 and 7) in the peripheral wall 91 of the left (upper in FIG. 5) shell part 30. The notch 90 has parallel opposed guide faces 92 (FIG. 7) spaced apart to snugly slidably guide therebetween the opposite guide rails 74 of the link member 51, and thus spaced at substantially at the maximum width of the link member. The thickness of the link member is guided for reciprocation between the peripheral edge 93 of the right (lower in FIG. 5) shell 31 and the width wall 94 (FIGS. 5 and 7) of the other shell part 30.

The central length axis LA (FIG. 10) of the link member intersects the central length axis MA of the motor shaft 52 at the axis SA of the output shaft 61 and stub shaft 83 (FIGS. 10 and 12), at an angle equal to the angle between the central length axis of the handle 12 and barrel 13 of the housing 11. Moreover, the length axes of the handle and barrel also intersect at the axis SA of the output shaft 61 when the drive unit 25 is installed in the handpiece housing 11 as hereafter discussed. In effect then, the link member longitudinal axis LA and motor shaft axis MA define the length axis of the barrel 13 and handle 12, respectively, when the drive unit 25 is installed in the handpiece housing 11.

The drive unit 25 is located within the handle 12, as follows. As seen in FIGS. 3 and 4, transverse ribs 95 are molded into the interior surface of the handle 12 at opposing locations in the left and right housing

parts 14 and 15 (FIGS. 2-4). For drawing convenience, only the ribs in the right housing part 15 are shown, the ribs in the left housing part 14 being compatible. The ribs 95 locate the drive unit 25 in the rightward/leftward direction in FIG. 2. Further, the drive unit shell bosses 84 and 85 (FIG. 5) protrude sideways from the drive unit shell and are pivotally received in corresponding hollow cylindrical bosses, one of which is shown at 96 in FIG. 2, and which extend toward each other from the interior of the left and right housing parts 14 and 15. The hollow cylindrical boss 96 of the left housing part 14 is not shown but is opposed to and compatible with the housing part 96 shown in the right housing part 15 of FIG. 2. The drive unit 25 is thus, except for the lateral positioning defined by the ribs 95, pivotally located within the handpiece housing 11 and is thus capable of some pivotal floating in the housing to achieve proper alignment of the longitudinal movement axis LA (FIGS. 7) of the link member 51 with respect to the barrel 13 and a pump unit 100 (FIGS. 2–4 and 16–18) located in the barrel 13 as hereafter discussed.

Pump Unit

Turning now to the pump unit 100, attention is directed to FIGS. 2-4 and 16-18. The pump unit 100 includes a bellows 101 including an axially expandable and contractible flexible bellows wall 114 (FIG. 18) and a forwardly extending, rigid, annular flange wall 102. Such flange wall 102 is loosely telescoped over a rigid rearwardly extending annular flange 103 of a rigid, forwardly extending coaxial bellows housing 104.

The bellows 101 and bellows housing 104 are preferably of molded plastics material. A resilient O-ring 105 (FIGS. 16 and 19) is snugly radially disposed between the radially opposed, axially extending annular flanges 102 and 103, to create a fluid seal therebetween and hence between the bellows 101 and bellows housing 104, to prevent fluid leakage therebetween. The bellows 101 and bellows housing 104 have respective axially spaced radially extending steps 106 and 107 joined to the respective annular flanges 102 and 103 and axially spaced apart at a distance substantially greater than the diameter of the O-ring 105, as seen in FIG. 19. The axial extending flanges 102 and 103 and radially extending steps 105 and 106 define an annular chamber 110 in which the O-ring 105 is axially loosely, and radially snugly and sealingly, disposed. Note that the radially opposed surfaces of the axially extending annular flanges 102 and 103 are cylindrical, such that neither has an annular groove in which the O-ring seats. Thus, the O-ring is free to roll on the radially opposed cylindrical surfaces of the axially extending flanges 102 and 103 and the O-ring 105 does not significantly interfere with axial separation of the bellows 101 and bellows housing 104 from each other.

Instead, such axial separation is prevented, as hereinafter further discussed, by a forwardly-rearwardly (leftwardly-rightwardly in FIG. 2) spaced pair of ribs 111 (FIG. 2) extending radially inward from the interior wall of the right housing part 15 and a corresponding, laterally opposed pair of mirror imaged ribs (not shown) extending laterally inward from the interior wall of the left housing part 14. Such ribs 111 are also schematically indicated in FIG. 18.

The rear (right in FIG. 19) end of the bellows housing axial flange **103** abuts the radially extending step **106** of the bellows **101** and the forward (leftward in FIG. 19) end of the bellows axial flange **102** axially abuts a radial flange **112** which extends radially outward from and forwardly from the bellows housing step **107**. The forward end of the bellows axial flange **102** thus radially overlaps the bellows housing step **107** in snug but axially slidable relation thereto. A small forwardly extending annular rib **113** protrudes forwardly from the bellows radial step **106** toward the O-ring **105** to prevent rearward escape of the O-ring **105** from the space between the axially extending flanges **102** and **103**, in the event of slight axial shifting of the bellows **101** and bellows housing **104** away from each other.

The above mentioned radially inward extending ribs **111** of the handpiece housing **11** snugly axially oppose and sandwich therebetween the bellows radial step **106** and bellows housing radial flange **112** to positively prevent axial separation of the bellows **101** from the bellows housing **104**, when the pump unit **100** is installed in the housing **11**.

The above-mentioned bellows wall **114** extends rearward from the inner periphery of the radially extending annular step **106** of the bellows **101** (FIG. 18) and consists of an axially collapsible and extensible, flexible, wave cross-section, peripheral wall **114**. The bellows wall **114** surrounds an axially expansible and contractible pumping chamber **115**. At the rear end of the bellows **101**, a radially extending drive end wall **116** closes the rear end of the bellows wall **114** and pumping chamber **115**. A stub **120**, having a radially

enlarged head 121, is fixed to and extends coaxially rearwardly from the drive end wall 116.

To axially reciprocatingly drive (repetitively axially contract and expand) the bellows 101, the above discussed link member 51 (FIG. 5) of the drive unit 25 has its fork 71 provided with a central, radially opening, generally U-shaped slot 122 (FIGS. 11–13). The slot 122 divides the fork 71 into a pair of tines 123 (FIG. 11). The slot 122 opens leftwardly in FIG. 2, namely away from the rightward housing part 15 and toward the leftward housing part 14. Thus, with the drive unit 25 located in the right housing part 12 as seen in FIG. 3, the pump unit 100 can be inserted into the rightward housing part 15, with the stub 120 (FIG. 18) inserted in the slot 122 of the fork 71 (FIG. 11) so as to trap the tines 123 axially between the drive end wall 116 and head 121 of the bellows 101, as generally indicated in FIGS. 3 and 4. To prevent the bellows stub 120 from accidentally radially escaping out the open end of the slot 122 in the fork 71, the central portion 124 (FIG. 11) of the slot 122 is undercut by inward tapering of an intermediate portion 125 of the slot 122 as seen in FIG. 11. The tapered portion 125 of the slot 122 (FIG. 11) defines a snap fit detente for resiliently trapping the bellows stub 120 in the drive unit slot 122. Thus, to install the bellows stub 120 in the slot 122, the bellows stub 120 must be resiliently forced through the tapered portion 125 of the slot 122 and upon passing the latter, the stub resiliently snaps into the central portion 124 of the slot. The inner ends of the tapered portion 125 of the slot resiliently maintain the stub radially inboard thereof, in the central portion 124 of the slot 122.

The stub **120** and hence the bellows **101**, and indeed the entire pump unit **100**, is thus freely rotatable about its length axis with respect to the fork **71**, so that the circumferential orientation of the drive unit **25** and the pump unit **100** is determined by the location thereof in the housing. The drive unit **25** and pump unit **100** are thus, to an extent, free to circumferentially float with respect to each other, about the connection of the stub **120** and fork **71**, without interfering with the circumferential location of the drive unit **25** and pump unit **100** in the housing **11**. Further, the edges of the slot **122**, in particular of the central portion **124** thereof, are rounded in cross-section, as is the stub **120**, to permit a modest amount of angular adjustment between the length axes MA and LA of the drive unit **25** and pump unit **100** and to allow the drive unit **25** and pump unit **100** to easily settle into their proper operating positions in the housing **11**.

A cylindrical plug **126** is coaxially fixed to the interior side (left side in FIG. **18**) of the bellows drive end wall **116** by a coaxial, rearward extending, undercut pin **127** snap fitted in a forwardly (leftwardly in FIG. **18**) opening recess in the stub **120**. The plug **126** has a diametral slot **130** opening forward from its front end and which faces forward toward a resilient valve member **131** (FIGS. **16** and **18**) to maintain liquid communication between the central and radially outer portions of the pumping chamber **115**.

The bellows **101** is thus a single element which carries out four different functions, namely sealing at the forward end, changing the pump chamber size in the middle thereof, the rearend acts as a piston and as a drive point. In addition, the front annular flange **102**

helps locate the pump unit with respect to the housing barrel.

The pump unit **100** further includes a valve member **131**, which is a one piece member of suitable resilient material and which by itself constitutes the entire moveable inlet and outlet valve system for the pump unit **100**. More particularly, the valve member **131** comprises a short tubular central portion **132** (FIG. 18) which coaxially connects a forward (leftward in FIG. 18) tapering, duck bill type, outlet valve **133** and a rearwardly and radially outwardly extending umbrella type, inlet valve **134**. The umbrella valve **134** is annular and has a central opening **135** which communicates coaxially from the pumping chamber **115** in the bellows **101** forwardly through the tubular central portion **132** and outlet duck bill valve **133** of the valve member **131**.

The bellows housing **104** comprises a rear (right in FIGS. 18 and 18C) facing recess having a perimeter defined by the annular flange **103** of the bellows housing **104** and a rear facing radial wall **136** which defines the front end of the pumping chamber **115**. The umbrella valve **134** lies coaxially in the resulting recess **103, 136**. The forward facing perimeter **137** of the umbrella valve **134**, in its closed condition shown in FIGS. 18 and 18C, presses forward against the radial wall **136** to seal thereagainst. The valve member **131** is held against the right (rearward) movement away from the bellows housing wall **136** by axial interference between a rightward facing, radially outward extending, annular step **140** (FIG. 18C) at the rear (right) end of the duck bill valve **133**, and a radially inward extending, leftward facing, annular flange **141** of the bellows housing **104**. The radially inward di-

rected, annular flange 141 is axially interposed between, and forms a port 142 between, the rear facing recess 103, 136 and a coaxial, forwardly extending, cylindrical, irrigation liquid outlet conduit 143 (FIGS. 18 and 18C). The tubular central portion 132 of the valve member 131 extends snugly axially through the port 142.

To install the valve member 131 in the bellows housing 104, the tapered outlet duck bill valve 133 is pushed forward through the port 142, the bellows valve step 140 snaps forwardly (leftwardly in FIG. 18C) past the bellows housing flange 141, and the sealing perimeter 137 of the umbrella valve 134 is thereby pulled forwardly resiliently against the rearward facing bellows housing wall 136, leaving the valve member 131 with its duck bill valve 133 and umbrella valve 134 both in their closed condition shown in FIGS. 18 and 18C.

The bellows housing 104 further includes an annular liquid jacket 144 (FIGS. 18 and 18C) surrounding the rear portion of the liquid outlet conduit 143 and defining radially therebetween an annular liquid inlet chamber 145 (FIGS. 18, 18C and 19). The inlet chamber 145 communicates between a radial inlet port 146 (FIGS. 16 and 19), which opens radially outward through the side of the bellows housing 104, and an annular space 147 (FIG. 18C). The annular space 147 is bounded by the forward face 150 and tubular central portion 132 and sealing perimeter 137 of the umbrella valve 134 and the radial face 136 of the recess 103, 136 of the bellows housing 104.

Thus, a rightward pullback of the bellows head 121 axially expands the bellows, from its FIG. 18A posi-

tion towards its FIG. 18 position. This reduces the pressure within the bellows. This in turn keeps the duck bill valve 133 closed and pulls the sealing perimeter 137 of the umbrella valve 134 rightwardly away from the bellows housing recess radial wall 136 and draws liquid from the port 146 through the annular inlet chamber 145, around the perimeter 137 of the open umbrella valve and into the interior of bellows.

On the other hand, a leftward push forward of the bellows head 121 axially compresses the bellows from its FIG. 18 position toward its FIG. 18B position and raises the pressure in the bellows, to close the umbrella valve 134 and open the duck bill valve 133 and force a pulse of liquid out of the bellows forwardly through the duck bill valve 133 and liquid outlet conduit 143.

Irrigation liquid is drawn to the inlet port 146 of the bellows housing 104 through an elbow 151 (FIG. 19). The outlet end 152 of the elbow and the inlet port 146 are cylindrical, with the elbow outlet end 152 being a snug axially sliding fit in the inlet port 146. An axially elongate, annular groove 153 in the outer periphery of the elbow outlet 152 houses a seal ring, here an O-ring, 154 which bears sealing and rollingly on the radially opposed and surrounding surface of the inlet port 146 to prevent liquid leakage out of the elbow 151 at its interface with the inlet port 146. The elbow 151 is not mechanically interlocked with the inlet port 146 but can slide in and out with respect thereto. The elbow 151 is held in place with its outlet end 152 sealingly within the port 146 by bearing of a portion 155 (FIG. 4) of the handpiece housing barrel 13 against the outboard surface 156 of the elbow 151, with the pump unit installed in the handpiece housing

11. The elbow 151 here fixedly carries a pair of parallel fins 157 (FIGS. 16, 17 and 19). The fins 157 extend radially from the rear inlet end portion of the elbow 151 and axially sandwich therebetween the flanges 106 and 112 of the bellows 101 and bellows housing 104, at least to help the housing ribs 111 (FIG. 18) fins 157 prevent axial separation of the bellows and bellows housing. The housing ribs 111 and fins 157 are more or less evenly circumferentially located around the bellows 101 and bellows housing 104.

An elongate flexible irrigation liquid supply hose 160 (FIGS. 2, 4, 16, 17, 19, 22, 23, 25 and 29) has a forward end 161 which telescopes sealing and fixedly over the rear end 162 of the elbow 151 as seen in FIGS. 19 and 29. Although an annular barb is shown at 162 (for example in FIG. 19) a barbless, cylindrical end 162 is satisfactory. In the assembled handpiece, the irrigation liquid hose 160 extends rearward from the elbow 151 (FIG. 4) in the barrel 13 of the housing and angles downwardly and rearwardly along the bottom of the handpiece handle 12 to exit rearwardly and downwardly through a hole 163 (FIG. 2) in the bottom end wall 164 of the handpiece housing 11. A clamp plate 165 (FIGS. 2, 3 and 4) of bent cross-section has a perimeter groove 166 for receiving the edges of the hole 163 in the housing bottom end wall 164, such that the clamp plate 165 is trapped in and partly closes the hole 163 in the bottom end 164 of the housing handle 12 when the housing is fully assembled. A notch 167 (FIG. 2) in the rightward end of the clamp plate 165 permits exit therethrough of irrigation liquid supply hose 160 from the handpiece housing 11 and snugly and frictionally grips such hose, without crushing or collapsing it, so that such hose 160 cannot easily be pulled out of the housing 11 or off the elbow 151.

The irrigation liquid hose **160** has fixed on the outside thereof, as by extruding or molding integrally therewith, a smaller diameter rib **170** (FIGS. **2**, **16** and **17**). A plurality (here three) of insulated electrical conductors (wires) **171** have intermediate portions contained within and extending the length of the rib **170**. Forward end portions of the insulated wires **171** emerge from the forward end of the rib **170** and carry conventional electrically conductive connectors **175**. The forward end of the rib **170** extends through the notch **167** (FIG. **2**) and ends just inside the bottom portion of the handle **12** of the housing **11**, as seen in FIG. **4**. The forward ends of the conductors **171**, carrying the connectors **175**, extend into the lower portion of the handpiece handle **12** for purposes appearing hereinafter.

The insulated electrical conductors **171** extend along the length of the central portion of the liquid supply hose **160** and have rear ends provided with respective electrically conductive connectors **176** (FIGS. **22** and **29**), such that electric current can flow from a given rear connector **176** through its corresponding insulated electrical conductor **171** and to its corresponding front electrically conductive connector **175** in a conventional manner. Short rear portions of the conductors **171** are loose and moveable with respect to the liquid supply hose **160** as seen in FIGS. **22** and **29**.

The electrical connectors **175** and **176** are conventional crimp type connectors.

Instead of being molded in or otherwise constrained within the generally circular cross section rib **170** in FIG. **2**, the elongate central portion of the insulated electrical conductors **171** may be fixed side by

side, in a flat array, to the outside of the liquid hose **160**, as shown in FIGS. **22** and **29**, and such can be accomplished by adhesive bonding or by any other convenient means.

The hose **160, 170** thus serves the dual use of conveying both irrigation liquid and electric operating power.

The length of the central portion of the liquid hose **160**, to which the insulated conductors **170** are fixed, preferably extends several feet (for example 8 to 10 feet) from the handpiece **10**. The rear end **177** (FIGS. **22** and **23**) of the liquid hose is here provided with a fitting **180** of hollow tubular construction open to axial liquid flow therethrough. The fitting **180** comprises a forward end portion **181** (FIG. **23**) fixed sealingly telescoped in the rear end **177** of the liquid hose **160**, a square central flange **182** (FIG. **22**) and a rear end portion (or "spike") **183** having a sharpened tip **184**. The tip **184** is capable of conventional insertion into a conventional source S (FIG. **22**) of irrigation liquid, for example a conventional supply bag, for conveying irrigation liquid therefrom forward into the hose **160**. The square flange **182** prevents rotation of the fitting **180** in the casing **191**, which helps when removing the spike **183** from the liquid supply bag. In the embodiment shown, the rear end portion **183** is covered by a protective cap **185** prior to use so that the sharpened tip **184** will not accidentally be dulled.

Thus, the length of the liquid supply hose **160** allows the irrigation liquid source S to be located at a distance from the handpiece and thus out of the way of the surgical personnel at the operating table where the handpiece **10** is to be used.

Electrical Power Supply Unit

To provide operating electrical power to the motor **36**, a compact, self contained electrical power supply unit **190** (FIGS. **20–25**) is fixed on the rear end portion **177** of the liquid hose **160**, and is thus located remotely from the handpiece **10**, adjacent to the source S of irrigation liquid.

The power supply unit **190** comprises a casing **191** preferably of rigid molded plastics material. The casing **191** here comprises a relatively deep, substantially rectangular pan **192** (FIG. **2**) whose top (as oriented in FIGS. **22** and **23**) is fixedly closed by a cover **193**. The pan **192** has front and rear end walls **194** and **195** (FIGS. **23**, **23A** and **24**) having fixed upward opening slots **200** each defined by a laterally spaced, opposed pair of U-shaped flanges **201** (FIGS. **23A** and **23B**). The slots **200** are undercut in that each has a mouth **202** laterally narrower than the remainder of the slot **200** and communicating between the remainder of the slot **200** and the interior cavity of the pan **192**. The undercut slots **200** are of constant cross-sectional size and shape vertically (i.e. into and out of the page in FIG. **24** and up and down in FIG. **23**).

For convenient reference in the drawings, the reference numerals **200** and **201** are suffixed, so that the undercut slots and U-shaped flanges on the front pan wall **194** are indicated by the reference characters **200F** and **201F** and the undercut slots and U-shaped flanges on the rear pan wall **195** are indicated at **200R** and **201R**.

The U-shaped flanges **201F** defining the slots **200F** on the forward end wall **194** start substantially from

the pan bottom wall **196** and extend a bit less than half way up the front end wall **194**.

On the other hand, the U-shaped flanges **201R** of the slots **200R** on the rearward end wall **195** of the pan are spaced above the bottom wall **196** of the pan upon respective block-like pillars **203** which define an up-facing bottom **204** for each of the U-shaped flanges **201R** on the rear pan wall **195**.

Rising from bottom wall **196** of the pan between the two central pillars **203** to a height below the bottoms **204** of the slots **200R** thereof, is a central block **205** from which forwardly extends, along the pan bottom wall **196**, a T-shaped flange **206** (FIG. **23B**) of constant cross section vertically and defining a pair of vertically open and laterally oppositely opening grooves **207** disposed immediately forward from the two central pillars **203** on the rear pan wall **195**.

Two such undercut slots **200F** are spaced symmetrically side by side on the front pan wall **194**. Similarly, and at the same effective lateral spacing, two such slots **200R** are spaced laterally side by side on the pan rear wall **195**.

Springy, electrically conductive sheet metal battery contacts of three different kinds are indicated at **210** and **211** and **212** and FIGS. **26**, **27** and **28** respectively.

A pair of such contacts **210** are provided and each comprises a generally rectangular foot **213** adapted to snugly slide down into a respective undercut slot **200F** at the pan front wall **194**. Each foot **213** is provided with resilient toes **214** angled out of the plane of the

foot 213 and adapted to bite against the interior of the corresponding undercut slot 200F to fix the corresponding battery contact 210 in place therein.

Similarly, each of a pair of battery contacts 212 (FIG. 28) has a resilient fork-shaped foot 215 adapted to fit snugly and slidingly down into the corresponding undercut groove 200R at the rear wall 195 of the pan 192 and with springy toes 216 for fixedly gripping the interior of the corresponding undercut slot 200R.

In a generally similar manner the single, low speed battery contact 211 (FIG. 27) has a resilient U-shaped foot 217 for sliding down over the T-shaped flange 206 (FIG. 23B), with springy toes 218 bent out of the plane of the foot 217 for bitingly engaging the walls of the grooves 207 of the T-shaped flange 206.

Each of the battery contacts 210, 211 and 212 thus slides with its corresponding foot into the desired location with respect to the grooves 200F, 200R and 207 and locks fixedly therein. This is generally indicated in FIGS. 22–24. The battery contacts 210, 211 and 212 have respective resilient fingers 221, 222 and 223 (FIGS. 26, 27 and 28 respectively), two each for the battery contacts 210 and 211 and one each for the battery contacts 212. Such fingers 221, 222 and 223 protrude from the respective slots 200F, 200R and 207 into the interior of the pan 192 for electrically contacting batteries 230 (FIG. 22) to be housed in the pan 192. Further, the battery contact 211 and each of the battery contacts 212 (FIGS. 27 and 28 respectively) have an upstanding terminal (224 and 225 respectively) of simple rectangular shape for releasable telescoped engagement within a respective one of the

connectors **176** at the rear ends of the three insulated electrical conductors **171** (FIG. **22**).

Turning now to the arrangement of the batteries **230** within the pan **192**, one embodiment according to the invention advantageously uses batteries of a kind widely available in retail stores, namely AA size alkaline batteries. In addition to their wide availability to the public, these batteries advantageously are inexpensive, have a long shelf life and provide full operating voltage until almost fully discharged. In the embodiment shown, eight such batteries **230** are provided and are individually indicated at **B1**, **B2**, **B3**, **B4**, **B5**, **B6**, **B7** and **B8**. As shown in FIGS. **22–24**, ribs **231** extending circumferentially within the pan **192** cradle the batteries **230** fixedly but removably within the pan **192**. The polarity of the eight batteries is indicated by "plus" signs marked thereon. As seen in the drawings, the batteries **230** are arranged in four rows of two head-to-tail batteries each. Four of the batteries **230** lie in the bottom (FIGS. **22** and **23**) of the pan in two rows of two each and the remaining four batteries **230** lie on top of those.

The ends of the battery rows bear variously on the above discussed battery contacts **210**, **211** and **212** as generally indicated for example in FIG. **22** and also in the schematic circuit drawing in FIG. **22A**. More particularly, the four batteries **B1**, **B2**, **B3** and **B4** defining a vertical plane nearest to the viewer in FIG. **23** are connected in series from the near connector **212** leftwardly through the top row of batteries, down through the near upstanding connector **210** and thence rightwardly through the bottom pair of batteries to the lower rear connector **211**. The remaining four batteries **B5–B8** are arranged in a vertical plane

behind above-mentioned batteries **B1–B4**. More particularly, the batteries **B5–B8** connect in series from the far side of the lower rear connector **211** forwardly (leftwardly in FIG. **22**) to the far connector **210**, upwardly therethrough, and then rearwardly back to the far upper connector **212**.

The cover **193** (FIGS. **23** and **25**) has plural, laterally extending, depending ribs **232** (FIGS. **23** and **25**) intended to seat upon the uppermost batteries **B1**, **B2**, **B7** and **B8** and fix the batteries **B1–B8** in the pan with the cover **193** fixed in its normal closed position atop the pan **192**. The cover is fixedly securable atop the pan by any convenient means, such as snap fit connectors, a portion of which are generally shown in **233** in FIG. **22**, and generally like those discussed above with respect to the handpiece housing **11**, as at **16**, and as generally discussed with respect to the drive unit shell **26**, as at **32**, **33**.

The aforementioned rear end **177** of the hose **160** extends through the casing **191** along the horizontal parting plane between the pan **192** and cover **193**, and so lies close adjacent the topmost batteries **B1**, **B2**, **B7** and **B8**.

Hollow front and rear bosses **234** and **235** (FIGS. **23** and **25**) extend forward and rearward respectively, from the casing **191**. At the parting plane between the pan **192** and cover **193**, the bosses **234** and **235** are notched (for example at **236** in FIG. **22**) for extension therethrough of the rear end **177** of the liquid hose **160**. The rear hollow boss **235** is sized and shaped to receive radially therein the square flange **182** (FIG. **23**) on the rear end of the liquid hose **160**, and thereby axially fix the rear end of the liquid supply hose **160**

within the casing 191 and nonrotatably fix the fitting 180 to the battery casing 191. The notch 236 in the front boss portion 234 on the cover 193 is indented by one or more small recesses 237 for receiving axially therethrough the rib 170 containing the insulated electrical conductors 171, whose rear end connectors 176 are respectively fixed to the terminals 224 and 225 of the battery contacts 211 and 212.

Trigger Unit

The handpiece 10 further includes a trigger unit 240 (FIGS. 2–4) for controlling actuation of the motor 36. The trigger unit 240 comprises a generally L-shaped trigger member 241 (FIGS. 2, 4 and 4A) comprising an elongate trigger lever 242. The upper, forward (leftward in FIGS. 2 and 4) end of the trigger lever is pivoted by laterally extending integral pins 243 pivotally receivable in suitable holes in laterally opposed bosses 244 (one of which is shown in FIG. 2) in the opposing lower edges of the housing parts 14 and 15, near the rear end of the barrel 13. Snapping together of the two housing parts 14 and 15 thus captures the pivot pins 243 and pivotally mounts the trigger with respect to the handpiece housing 11.

The trigger lever 242 includes a transverse ridge 245 (FIG. 4) near to but spaced rearwardly from the pivot pins 243 and facing the underside of the barrel 13 and adapted to bear on the underside thereof in the manner of a fulcrum. By far the major length 246 of the trigger lever 242 is to the rear (right in FIG. 4) of the fulcrum ridge 245. This rearward trigger part 246 is relatively rigid in the portion thereof spaced at least somewhat to the rear of the fulcrum ridge 245. Such rigidity is assisted by a forward facing longitu-

dinal reinforcement rib 247 extending rearward along the front face of the trigger lever 242 from a point near the fulcrum ridge 245. The front of the trigger lever 242, to the rear of the fulcrum ridge 245 is, in the embodiment shown, provided with transversely extending ribs 248 to provide the user with a non-slip grip of the trigger lever 242.

The trigger lever 242 is bendable near the fulcrum ridge 245, both to the front and rear thereof, in a resilient manner. In this way, the resilience of the trigger lever tends to hold it in its forward, inactive position shown in FIG. 4, with the fulcrum ridge 245 bearing on the underside of the handpiece barrel 13. On the other hand, when the user grips the handle 12 and squeezes the trigger lever 245 toward it, in the direction indicated by the arrow TA in FIG. 4, the trigger lever bends in the region of the fulcrum ridge 245, tending to straighten from its relaxed convexly forwardly curved configuration of FIG. 4, so that the rear face of the trigger lever can be pulled into the dotted line position 242P, substantially against the front face of the handle 12. Upon release of the trigger by the user, the natural resilience of the trigger lever 242 unbends it back to its solid line forward position shown in FIG. 4. Accordingly, the trigger naturally returns forward to its non-operative position without need for a separate return spring.

The trigger arm 251 fixedly carries a thumb 250 (FIG. 4A) intermediate it ends in the housing handle 15 and which interferes with the housing wall adjacent the hole 252, to prevent the resilient restoring force of the trigger lever 242 from pulling the trigger arm 251 leftwardly (FIG. 4A) out of the housing handle 12.

A plank-like switch contact support arm **251** (FIGS. **2**, **4** and **4A**) protrudes substantially at a right angle from the rear, or bottom, end of the trigger lever **242** and extends upwardly and rearwardly (in FIG. **4**) into the lower portion of the handle **12**, loosely through a hole **252** (FIG. **4A**) in the opposing bottom wall of the handle. A plate-like electrically conductive contact blade **253** fixedly extends through the thickness of the arm **251**, and has a front portion exposed towards said motor and a rear portion exposed toward the bottom end **164** of the handpiece handle.

A pair of rectangular posts **255** and **256** protrude fixedly into the interior of the handle **12** from the inside of the right housing part **15**, about midway between the drive unit **25** and the housing bottom end **164** (FIGS. **4A** and **4B**). Each post **255** and **256** includes a T-shaped flange **260** extending substantially forward toward the drive unit **25**. Each T-shaped flange **260** defines a pair of oppositely facing grooves **261** (FIG. **4C**).

Electrically conductive, spring-like metal contacts **262** and **263** (FIGS. **4A** and **4C**) each have a substantially U-shaped foot **264** for reception on the T-shaped flange **260** of the corresponding posts **255** and **256**. The contacts **262** and **263** further each have a substantially rectangular, projecting terminal **265** for telescopic fixing thereon, in electrically connected relation, a corresponding one of the front connectors **175** of the three insulated electrical conductors **171**. The electrical contacts **262** and **263** further have respective, generally L-shaped, plate-like, flexible contact leaves **266** and **267** (FIG. **4C**). The contact leaves **266** and **267** extend toward the drive unit **25** as seen in FIG. **4A**.

Protruding rearwardly from the motor **36** are a pair of electrically conductive contacts **270** and **271** (FIGS. **4A** and **9**). The contact **271** is a conventional terminal (like those at **224**, **225** and **265**) for receiving one of the front connectors **175** in fixed and electrically conductive relation thereon.

In contrast, the contact **270** is an elongate, springy rectangular piece, bent intermediate its ends in dog-leg fashion, and angling from the rear end of the motor **36** rearwardly and somewhat rightwardly (in FIG. **4A**) to a free end portion spaced near the contact leaves **266** and **267**.

Gradual pressing of the trigger lever **242** toward the handle housing (rightwardly in FIGS. **4** and **4A**) moves the arm **251** and hence the contact blade **253** progressively further into the handle **12** through a series of positions, three of which are indicated in broken lines at **253A**, **253B** and **253C** in FIG. **4A**.

The free (rightward in FIG. **4A**) end of the arm **251** is beveled at **272** to help it ride over the contacts **266** and **267** as the trigger lever **242** is sequentially squeezed more and more toward the handle **12**. The arm **251** is progressively resiliently bent, like a leaf-spring, as its free end rides over the fixed contacts **266** and **267**, to firmly press its contact blade **253** against the latter.

Thus, as the trigger lever **242** is pressed toward the handle **12**, the beveled free end of the arm **251** rides over the contact leaf **266** past its dotted line position **253A** and toward its dotted line position **253B**. As the free arm end approaches position **253B**, the contact blade **253** slides into electrical contact with

the contact leaf **266** and the motor contact **270** to establish electrical connection therebetween. The motor contact **270** resiliently bends to allow continued travel of the contact blade **253** and arm **251** further into the handle, as indicated in dotted line at **270B**, and to press firmly against the contact blade **253**. Given only a light pull on the trigger lever **242**, the arm **251** and contact blade **253** tend to stop in the position indicated in dotted lines at **253B**, by reason of the free end of the arm **251** colliding with the contact leaf **267**. In this "B" position, electric current is fed to the motor **36** only from half the battery collection, namely batteries **B1**, **B2**, **B3** and **B4** in FIG. **22A**. The motor **36** thus runs at only a preselected fraction of its full speed and the pump unit **100** outputs irrigation liquid pulses at a desired frequency and amplitude, which are less than the maximum available. The apparatus is thus operated in its low output mode. The colliding of the free end of the trigger arm **251** with the contact leaf **267** gives tactile feedback to the user, that the low output mode of the handpiece has been selected.

Further pulling in of the trigger lever **242** by the user causes the beveled free end of the arm **251** to bend rightwardly (FIG. **4A**) the contact leaf **267** to a dotted line position indicated at **267C**, allowing the free end of the arm **251** to override the contact leaf **267**, such that the contact blade **253** moves into its "full-pull" dotted line position **253C** and further bends the motor contact **270** its dotted line position **270C**. In this final position, the contact blade **253** establishes electrical contact between the motor contact **270** and the contact leaf **267**, thereby applying the full series voltage of all eight of the batteries **B1-B8** to the motor **36** to operate the latter at its full speed and thereby drive the pump unit **100** at its full output, namely

to provide irrigation liquid pulses out of the pump unit **100** at maximum pulse amplitude and frequency.

When the user releases the trigger lever **242**, the resiliently bent trigger lever **242**, due to its inherent resilience, springs back from its fully pulled-in position indicated in broken lines at **242P**, to its solid line rest position indicated at **242** (FIG. 4A).

Suction Hose

A flexible suction hose **280** (FIGS. 2 and 3) is led along within the housing (within the lower part of the housing in FIG. 3) past the drive unit **25** and pump unit **100**. The above-mentioned clamp plate **165** includes a tubular structure molded thereinto and defined by a forward nipple **282** in the handle **12** and, in coaxial fluid communicating relation therewith, a rearward nipple **283** which extends rearwardly out of the bottom end **164** of the handpiece handle **12**. The rear end portion **281** of the suction hose **280** is sealingly and fixedly telescoped over the front nipple **282**. A conventional flexible hose, not shown, is conventionally and sealing telescopable over the rear nipple **283** for connecting same to a conventional suction source, as schematically indicated at SS in FIG. 3.

The front end portion **284** of the suction nose **280** is sealingly telescoped over a rearward opening nipple **285** on a short suction conduit **286** (FIGS. 2, 3, 16, 17 and 18). The suction conduit **286** (FIG. 18) is fixed side by side, in piggyback fashion, on the periphery of the irrigation liquid conduit **143** and hence is a part of (preferably an integral plastic molded part of) the bellows housing **104**.

The clamp plate **165** serves several purposes. It provides a suction hose connection, bears on the irrigation liquid hose where it enters the handpiece housing, and helps align the rear (rightward in FIG. 4) end wall portions of the housing halves as they are assembled together, and in so doing, is itself fixed on the housing. In addition, the clamp plate **165** is of one piece, preferably a plastic molding, and is partially recessed into the handpiece so that it does not make the handpiece look any bigger.

Tip Unit

A tip unit **291** (FIGS. 8, 8A and 8B) is releasably fixable on the front end of the handpiece **10** and extends forward therefrom for applying irrigation liquid pulses and/or suction to a surgical site indicated schematically at SU in FIGS. 8 and 8B. The tip unit **291** (FIG. 8) comprises a coupling **292**, a front cover **293** fixed to the front of the coupling **292**, and an elongate hollow wand **294** extending forwardly from the coupling and front cover for aiming at a surgical site SU. The coupling **292**, cover **293** and wand **294** are preferably one piece molded plastic units. The wand **294** is preferably of clear plastics material.

The tip unit **291**, and more specifically the coupling **292**, is releasably fitted in fluid tight relation to the front of the bellows housing **104** of the pump unit **100** and is releasably latched within the open front end of the handpiece housing barrel **13** as hereinafter discussed.

More particularly, the coupling **292** (FIG. 8) comprises a shallow, forward opening cup **295** having a flat base wall **296** from which forwardly extends a

shallow peripheral wall **297**, thereby defining a forward opening recess **300**. Coaxial irrigation liquid nipples **301** and **302** extend fixing rearwardly and forwardly, respectively, from the base wall **296** and together define a coaxial bore **303** therethrough and through the base wall **296**. The rear nipple **301** is snugly but slidably receivable rearwardly into the open front portion of the liquid outlet conduit **143** of the bellows housing **104**. An O-ring **304** seats in an annular groove outward facing on the rear nipple **301** and sealingly engages the interior of the liquid outlet conduit **143** to prevent irrigation liquid leakage therebetween.

The wand **294** includes a coaxial, relatively small diameter, irrigation liquid outlet tube **305** which at its rear end is telescoped fixedly and sealingly within the bore **303** of the front and rear nipples **301** and **302** for receiving a pulsed flow of irrigation liquid from the irrigation liquid outlet conduit **143** of the bellows housing **104**.

The coupling **292** further includes a suction nipple **306** fixedly extending rearward from the base wall **296** in spaced parallel relation with the irrigation liquid nipple **301**. The suction nipple **306** is snugly insertable rearwardly coaxially into the front opening suction conduit **286** of the bellows housing **104**. An O-ring **310** is axially sandwiched between the rear end of the suction nipple **306** and a front facing annular step **311** at the rear end of the suction conduit **286** to prevent leakage therebetween.

The coupling **292** further includes a leaf spring-like, generally U-shaped latch arm **312** which extends rearward from the peripheral portion of the base wall

296, curves radially outwardly and forwardly, and extends forward past the front cover 293, in radially outwardly spaced relation from the wand 294. A wedge-shaped, transverse ridge 313 on the exterior base of the latch arm 312 is approximately centered between the front and rear ends of the latch arm. A circumferentially extending, radially inward protruding rib 314 (FIGS. 2, 3 and 8) on the interior face and at the open front end of the right housing part 15 (at the front end of the barrel 13) opposes the latch arm 312, immediately ahead of the ridge 313, with the tip unit 291 installed on the front end of the handpiece 10 as shown in FIG. 8. The ridge 313 has a front facing step which abuts interferingly with the housing rib 314 to releasably block removal of the tip unit from its installed condition shown in FIG. 8. To remove the tip unit from the front end of the handpiece, the user simply presses radially inward against the forward protruding end portion 315 of the springy latch arm 312, sufficient to radially inward displace the ridge 313 out of interfering relation with the rib 314 and thereby unlatch the tip unit from the front end of the handpiece. This allows forward removing the tip unit 291 from the open front end of the handpiece barrel 13 and removing of the irrigation liquid and suction nipples 301 and 306 from the liquid outlet conduit 143 and suction conduit 286 of the bellows housing 104.

The tip unit 291, or any alternative tip unit having a substantially identical coupling and front cover, can be installed operatively on the front end of the handpiece 10 by inserting same into the open front end of the handpiece barrel 13 so that the nipples 301 and 306 enter the liquid and suction conduits 143 and 286 respectively, to their position shown in FIG. 8. During this installation, the forward facing slope of the wedge

cross-section transverse ridge **313** slides rearwardly past the housing rib **314**, bending the springy latch arm **312** radially inward as generally indicated by the arrow L in FIG. 8, so that the wedge cross-section ridge **313** can snap rearwardly past the rib **314** at the open front end of the housing barrel **13**. Thus, the tip unit **314** can be slid axially into the front end of the barrel **13** and upon reaching its innermost position latches itself against unintended removal. In its installed condition of FIG. 8, the tip unit is substantially rigidly fixed with respect to the front end of the bellows housing **104** and hence with respect to the handpiece barrel **13**.

The front cover **293** (FIG. 8) comprises a plate **320** which extends radially of the wand **294** and of the length axes of the barrel **13** and the pump unit **100**. The peripheral shape of the plate **320** conforms to the cross-sectional shape of the front end of the barrel **13**, so that the perimeter of the plate **320** is substantially flush with the outer periphery of the open front end of the barrel **13**, and so that the plate **320** effectively covers the open front end of the barrel **13**. The peripheral shape of the plate **320** and cross-sectional shape of the front end of the barrel **13** in one embodiment is generally D-shaped, with a generally flat underside and a convexly curved top and sides. The plate **320** is not intended to seal the open front end of the barrel **13** and so need not tightly abut same. Since the peripheral wall **297** of the cup **295** fits easily within the open front end of the barrel **13**, the plate **320** extends radially outwardly beyond the cup **295**, as seen in FIGS. 8, 8A and 8B.

The front cover **293** includes an annular flange **322** extending axially rearwardly therefrom, radially

snugly into the cup **295** of the coupling **292** to bottom rearwardly and sealingly against a resilient gasket **321** which is disposed against the front face of the base wall **296** of the cup **295**. Respective holes in the gasket **321** loosely surround the front nipple **302** and leave fully open the communication between the interior of the suction nipple **306** and the interior of the cup **29**. The front cover **293** further includes a further annular flange **323** extending fixedly and forwardly from the plate **320** in coaxial alignment with the through hole **324** in the plate **320**.

The rearward annular flange **322** of the front cover **293** is fixedly secured within the cup **295** of the coupling **292** by any convenient means, for example by snap fit connectors on the opposing faces of such flange **322** and the peripheral wall **297** of the cup **295**. For example, the cup peripheral wall **297** may be provided with several circumferentially spaced rectangular holes **325** (FIGS. 8A and 8B) for snap fit reception therein of small radially outward extending protrusions schematically indicated at **326** on the outside of the rearward annular flange **322**.

The wand **294** further includes a relatively large diameter elongate suction tube **330** (FIGS. 8A and 8B) which loosely coaxially surrounds the irrigation liquid outlet tube **305** (FIG. 8) and extends substantially to the front end of the latter. The rear end portion **331** of the suction tube **330** is radially enlarged to provide a radially shallow, axially elongate flange protruding radially outward therefrom and which is axially trapped between the plate **320** and the gasket **321** backed by the base wall **296**. This serves to rigidly fix the suction tube **330** with respect to the coupling **292** and front cover **293**. A port **332** in the sidewall of the

suction tube 330 near its rear end communicates with a loosely surrounding annular chamber 333 defined between the plate 320 and base wall 296 of the front cover 293 and coupling 292 respectively.

The front end of the irrigation liquid tube 305 is held coaxially fixed within the front end portion of the surrounding suction tube 330 by any convenient means, such as radial, circumferentially spaced, webs 334 (FIG. 8). Accordingly, with a tip unit 291, of the general type above described, installed on the front end of the handpiece, as shown in FIG. 8, irrigation liquid pulses from the pump 100 pass forwardly within the liquid tube 305 and are projected from the front (left in FIG. 8) end thereof, as schematically indicated by the arrows PL. At the same time, liquid and particulate debris at the surgical site SU are drawn into the front (left in FIG. 8) end of the suction tube 330, pass rearwardly along the length thereof, through the port 332 into the chamber 333 and rearwardly through the nipple 306 and suction nipple 285.

With the exception of a few components such as the motor 44, the various electrically conductive contacts, the elongate insulated conductors, the various seal rings (for example 105, 154, 304 and 310, the gasket 321, as well as the suction and irrigation liquid hoses, the remaining major components, while possibly manufacturable of a variety of materials, are economically manufacturable of available molded plastics materials. For example, the valve member 131 may be of rubber or a synthetic substitute or similar resilient plastic. Similarly, the bellows 101 is preferably molded of a suitable resilient plastic material capable of the bellows expansion and contraction movements shown the drawings. The trigger unit 240 and the latch arm 312,

while of substantially rigid plastics material, are elastically bendable to the extent required to suit the present description. Similarly, components to be snap-fitted together are substantially rigid but have sufficient resilience to permit the required described snap fitting.

The present invention can be constructed at relatively low cost and is thus practically manufacturable as a disposable tool, both the handpiece **10** itself and the accompanying electric power supply unit **190** being disposable after use with a single surgery patient.

OPERATION

The apparatus is quickly and easily assembled. The drive unit **25** (FIG. **12**) is assembled by, in effect, "dropping in" elements in proper sequence into the right (lower in FIG. **12**) shell **31** and covering same with the other shell **30**. More particularly, output gear **60**, face gear **54** and motor **36** (with attached pinion gear **53** and electric contacts **270** and **271**) are "dropped" into their respective locations in the upturned shell part **31**, in that sequence. The rectangular shaft **61**, topped by the eccentric member **62**, drops into the corresponding hole in the output gear **60** and the link member **51** drops onto the eccentric member. The other shell part **30** is then snap fitted over the filled shell part **31**, completing the drive unit **25**.

The pump unit **100** is assembled by coaxially-telescoping together its elements shown in FIG. **18** and then plugging into the inlet port **146** (FIG. **19**) the elbow **151** with the O-ring **154** and hose **160** assembled thereon.

The stub 120 (FIG. 18) of the drive unit 100 can then be snapped into the slot 122 of the drive unit fork 71 (FIG. 2) to connect the drive unit 25 operatively to the pump unit 100. The suction hose 280 can then be connected to the pump unit nipple 285 and to the nipple 282 on the clamp plate 165. Thereafter, the two assemblies above described can be laid into the rightward (FIG. 2) housing part 15 in the following order, namely liquid hose 160 (FIG. 4), drive unit 25 and pump unit 100 (FIG. 3) and, last, suction hose 280 and clamp plate 165.

The trigger unit 240 is then placed, with its rightward (FIG. 2) pivot stub 243 located in the corresponding boss 244 in the rightward housing part 15, and its arm 251 inserted through the hole 252 (FIG. 4A) into the interior of the handle portion of the rightward housing part 15, as seen in FIGS. 4 and 4A. The trigger arm 251 is "covered" by the rear portion 281 of the suction hose 280 in FIG. 3. The electrical contacts 262 and 263 are placed on their respective posts 255 and 256 in the rear portion of the rightward housing part 15 and the three forward electrical connectors 175 are secured respectively to the mentioned contacts 262 and 263 and the motor contact 271 (FIG. 4A). Thereafter, the leftward (FIG. 2) housing part 14 can be snap fitted to the rightward housing part 15 to close same and enclose the above mentioned apparatus, shown in FIG. 3, therein.

In the thus assembled handpiece, the drive unit is fixedly located by engagement of its drive axis bosses 84 and 85 (FIG. 5) in corresponding bosses in the housing parts 14 and 15 (see for example at 96 in housing part 15 in FIG. 2). Location of the drive unit 25 is assisted by the ribs 95 within the housing parts

14 and 15 and by snug resilient engagement of the drive unit 25 by the hoses 160 and 280 which flank it.

The drive unit shell 26 is configured to maintain the proper tolerances between meshing gears and related parts. Location of all the drive unit parts in the drive unit shell 26 reduces the need to maintain close tolerances in the larger and less specialized handle housing 11. Even the housing tolerances, for locating the pump unit 100 with respect to the drive unit 25 in the housing 11, need not be close since the bellows 101 are flexible enough to bend or otherwise distort to absorb minor mis-alignment or angulation of the reciprocation axis of the link member 51 with respect to the length axis of the pump unit 100. Indeed, the ribs 95 in the housing 11 permit pivoting of the drive unit 25 about the axis of the bosses 96 to allow the drive unit 25 and pump unit 100 to settle into their own working relative orientation. Accordingly, the precision in the handpiece housing 11 can be concentrated in aspects of fitting together of the two housing halves.

The electric power supply unit 190 (FIG. 22) is quickly and easily assembled. More particularly, the feet of the respective battery contacts 210, 211, 212 (FIGS. 26–28) are slid downward into their respective grooves (FIGS. 23A and 23B) in the pan 192 (FIG. 22) with their protruding toes resiliently gripping the sides of the grooves. The rear connectors 176 are connected to the battery contact fingers 224 and 225 in the order shown in FIG. 22A. The batteries B1-B8 are then slipped down into the pan in the orientation shown in FIG. 22 and into electrically conductive engagement with the battery contacts 210, 211 and 212 indicated in FIG. 22A. The rear portion of the liquid

hose **160** is laid atop the batteries as indicated in FIG. **23**, with the square flange **182** nonrotatable in the boss **235**, and the cover **193** is snap fitted atop the liquid hose **160** and battery filled pan **192**, as shown in FIG. **23**, to complete assembly of the power supply unit. The cap **185** is pressed onto the sharpened tip **184** to protect it prior to use.

The result is a disposable pulsed irrigation handpiece unit which is entirely self-contained, including its own power supply, and which is ready for use upon having its sharpened tip **184** plugged into a conventional irrigation liquid supply bag or the like, and a conventional manner.

It should be noted that virtually the entire handpiece **10** and power supply unit **190** can be assembled without need for any adhesives, the parts going together with friction or snap fits or, in the case of the joinder of the bellows housing **104** to the bellows **100** and elbow **151**, by being held together by surrounding structure which in turn is snap fitted together. This greatly eases and speeds assembly. A minor exception is that the fitting **180** is here adhesively fixed to the hose **160**.

To use the handpiece assembly in surgery, the cap **185** (FIG. **23**) is removed from the pointed tip **183**, which is then plugged into a standard output fitting on a conventional irrigation liquid supply bag. The power supply unit **190**, being fixed to the rear end of the irrigation liquid hose **160**, can be allowed to simply hang from the irrigation liquid supply bag (not shown but schematically indicated at S in FIG. **22**). By providing a substantial length of irrigation liquid hose **160** (for example **10** feet), the liquid supply bag S and

power supply unit **190** can be located well out of the way of the surgical team during use of the handpiece **10** at the surgical site. Even then, the power supply unit **190** is compact as compared to the adjacent conventional irrigational liquid supply bag (being very little larger than the eight conventional double AA batteries that it houses).

If suction will be desired at the surgical site, the handpiece nipple **283** (FIG. 3) can be connected by a conventional hose not shown to a conventional suction source SS (FIG. 3).

A variety of tip units **291** of differing characteristics (e.g. differing irrigation liquid spray patterns, etc.) may be made available for alternative mounting on the handpiece **10**. One example is shown in FIGS. 8, 8A and 8B.

In any event, the user selects a tip unit **291** having a wand **294** of desired configuration, and rearwardly inserts its coupling **292** into the front end of the handpiece **11**. More particularly, the nipples **301** and **306** of the tip unit are inserted coaxially rearwardly, in sealed relation (see FIG. 8) in the conduits **143** and **286** respectively of the bellows housing **104**. The resilient latch arm **312** enters the barrel **13** of the handpiece housing **11** adjacent to the bellows housing **104** until the plate **320** of the front cover **293** abuts the front end of the handpiece housing barrel **13**. In the last part of this tip installation movement, the wedge shaped ridge **313** (FIG. 8) on the latch arm **312** snaps past the rib **314** of the housing barrel **13** to positively prevent forward removal of the tip unit from the handpiece.

To use the apparatus for irrigation of a surgical site, the user grips the handpiece, either by the handle **12**, in a pistol-like manner, or where the barrel **13** joins the handle **12**, in a wand like manner. In either position, the user has one or more fingers that can bear on and press inwardly the trigger lever **242** from its inoperative rest position shown in solid line in FIG. **4A** forward and through its low speed and high speed positions indicated in broken lines at **253B** and **253C** in FIG. **4A**. In the first operative position **253B**, the blade **253** connects the low speed (here six-volt) contact **266** to the motor contact **270**. On the other hand, in the fully depressed condition of the trigger, indicated at **253C**, the blade **253** connects the high speed, **12** volt contact **267** with the motor contact **270**. Accordingly, the user can select between "off", lower power pulsing and high power pulsing.

In one embodiment pump stroke was about ¼". In one embodiment shown, the motor speed was about 15,000 rpm and the speed reduction afforded by the transmission was about 15-1, providing the eccentric with about 1,000 rpm speed.

Depending on the flow resistance of the particular tip unit attached to the handpiece, the liquid pulse frequency may change. In one example, a handpiece according to the invention produced about 1200 pulses per minute, dispensing about 1600 ml per minute of irrigation liquid in about 1.3 ml liquid pulses. The positive drive of the pump unit by the drive unit and the location of the pump unit, near the front end of the barrel **13** and in direct engagement with the tip unit, provides liquid pulses at the output of the tip unit which have sharp rise and fall slopes. Thus, the relationship of liquid pulse amplitude to time approxi-

mates a square wave form, more so than for example, the aforementioned device of U.S. Pat. No. 5,046,486. Further, the force applied to the pulses by the present apparatus is higher (somewhat above one Newton) than in that prior art device, at the full power position of the trigger.

In one embodiment according to the invention, a tab **316** (FIGS. **1** and 8B) extends forward from the front plate **320** of the front cover **293**, on the opposite side of the wand **294** from the latch arm **312**. To release the latch arm **312** from the housing **11**, the user can thus simply simultaneously grip with opposite fingers and pinch toward each other the latch arm **312** and tab **316**. In other words the tab **316** provides base toward which to pinch, or pull, the latch arm **312** to release the tip unit **291** from the handpiece **11**.

In the present invention, the liquid and suction nipples of the tip unit connect directly to the pump unit **100**, and do not contact any part of the handpiece housing **11**. Accordingly, neither the pump unit **100** nor tip unit **291** need fit with close tolerances the handpiece housing **11**. The connection of the tip unit to the handpiece housing is merely to latch the tip unit against loss from the handpiece housing and to casually cover the open front end of the handpiece housing. Accordingly, the liquid tight fit is between the nipples of the tip unit and conduits of the pump unit, not with the housing.

Although a particular preferred embodiment of the invention has been disclosed in detail for illustrative purposes, it will be recognized that variations or modifications of the disclosed apparatus, including the re-

arrangement of parts, lie within the scope of the present invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A pulsed irrigation surgical handpiece, comprising:

a hollow housing comprising a handle;

an elongate trigger extending along the front part of the handle;

an irrigation liquid tube extending within said handle from the bottom of said handle along the front part of said handle to the top of said handle;

an electric motor spaced between the top and bottom of said handle and located in the rear portion of said handle behind said irrigation tube;

a pump comprising an axially expandable and contractible bellows driven by said electric motor and connected to said irrigation liquid tube for pumping irrigation liquid for delivery to a surgical site, said motor having top and bottom ends and a rotatable shaft extending longitudinally from said top end toward the top of said handle, said motor bottom end being spaced above the bottom of said housing, a first electrical connector extending from the bottom end of said motor toward said housing bottom, said electrical connector being for connection to an electric battery, a portion of said trigger lying adjacent

said motor and being responsive to movement of said trigger for effecting an electrical connection from said motor to an electric battery for electrically energizing said motor.

2. A pulsed irrigation surgical handpiece, comprising:

a hollow housing comprising a handle;

an elongate trigger movably mounted on said housing;

an irrigation liquid tube extending along said handle;

an electric motor spaced between the top and bottom of said handle and located in said handle adjacent said irrigation tube;

a pump comprising a member driven by said electric motor, said pump being connected to said irrigation liquid tube for pumping irrigation liquid for delivery to a surgical site, said motor having a rotating pinion gear rotatably engagable with and driving a face gear, said face gear being operatively drivingly coupled to an eccentric member for rotation of said eccentric member by said motor, said driven member opposing said eccentric member, and a yoke located between a portion of said driven member and said eccentric member for converting rotation of said eccentric member to reciprocation of said portion of said driven member.

3. The apparatus of claim 2 in which said motor has top and bottom ends and a rotatable shaft extending

longitudinally from said top end toward the top of said handle, said motor bottom end being spaced above the bottom of said housing, a first electrical connector extending from the bottom of said motor toward said housing bottom, said electrical connector being for connection to an electric battery, a lower portion of said trigger lying adjacent said motor and being responsive to pull in of said trigger for effecting a further electrical connection from said motor to an electric battery for electrically energizing said motor.

4. The apparatus of claim 2 including a suction adapter comprising a tubular structure and an engaging member fixed transversely thereon for fixedly engaging a free end wall of said handle bottom, said tubular structure having interior and exterior ends respectively extending into and out of said housing, said housing including a barrel extending forward from the top portion of said handle and a tip on the front end of said barrel, said suction tube being connected to said interior end of said tubular structure and running in said handle and barrel to a portion of said tip, said irrigation liquid tube being clamped to said handle bottom free end wall by said engaging member.

5. A pulsed irrigation handpiece, comprising:

a handheld handpiece housing and an associated pulsed irrigation liquid outlet for applying liquid pulses to a surgical site;

a powered driver in said housing;

a reciprocatingly driveable, expansible chamber pump in said housing connected to said driver

and outlet for pumping pulses of irrigation liquid through said outlet, said pump having a bellows, said pump having a hollow body with an end toward said bellows, said end having a first annular flange, said bellows being cup shaped and having an end open toward said body and defined by a second annular flange, said flanges being substantially coaxially telescoped one over the other;

a resilient O-ring seal radially resiliently pressed between radially spaced annular surfaces of said telescoped annular flanges, said radially spaced annular surfaces being of axial length exceeding the diameter of said O-ring, said bellows having an expandable and contractible bellows wall and a radially outward extending annular portion defining an annular groove therebetween, said second annular flange extending forward beyond said radially outward extending annular portion, said handpiece housing having spaced inward projecting ribs fixed therein, said ribs respectively engaging said body and entering said annular groove to fixedly grip therebetween said body and bellows and so positively prevent axial separation of said telescoped annular flanges of said body and bellows.

6. The apparatus of claim 5 in which said pump body has a cylindrical irrigation liquid inlet port, said handpiece containing an irrigation liquid supply tube slidably fitted to said body irrigation liquid inlet port, said handpiece housing surrounding said body and liquid supply tube.

7. A pulsed irrigation handpiece, comprising:

a handheld handpiece housing and an associated pulsed irrigation liquid outlet for applying liquid pulses to a surgical site;

a powered driver in said housing;

a reciprocatingly driveable, expansible chamber pump in said housing connected to said driver and outlet for pumping pulses of irrigation liquid through said outlet, said pump having a bellows, said pump having a hollow body with an end toward said bellows, said end having a first cylindrical flange, said bellows being cup shaped and having an end open toward said body and defined by a second cylindrical flange, said flanges being substantially coaxially telescoped one over the other;

a resilient O-ring seal radially resiliently pressed between radially spaced cylindrical surfaces of said telescoped cylindrical flanges, said radially spaced cylindrical surfaces being of axial length exceeding the diameter of said O-ring and said O-ring being of circular cross-section and thereby free to roll axially between said radially spaced cylindrical surfaces in response to relative axial movement between said telescoped flanges without loss of sealing between said cylindrical surfaces.

8. The apparatus of claim 7 in which said body and bellows have radially outward extending annular end portions carrying said axially telescoped cylindrical flanges, said handpiece housing having radially inward projecting ribs fixed therein and axially spaced to fixedly grip axially therebetween said telescoped

annular ends of said body and bellows to positively prevent axial separation of said body and bellows.

9. The apparatus of claim 7 in which said pump has a rear end portion driven by said driver and a front end portion, said liquid outlet comprising an elongate tubular tip having a front end for delivering irrigation liquid pulses to a surgical site and a rear end releasably connected directly and in liquid pulse receiving relation to said pump front end portion and releasably mechanically latched directly to said handpiece housing.

10. The apparatus of claim 7 in which said pump body has a cylindrical irrigation liquid inlet port, said handpiece containing an irrigation liquid supply tube having an elbow slidably fitted into said body irrigation liquid inlet port, said elbow carrying a surrounding seal ring bearing rollingly and sealing on the surrounding surface of said inlet port, said handpiece housing loosely surrounding said body and liquid supply tube and elbow and backing said elbow against sliding out of said inlet port.

* * * * *

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

Bruce A. Lehman

Acting Director of the United States Patent and Trademark Office

Brenda Moore

NOTICE

If the application for this patent was filed on or after December 12, 1980, maintenance fees are due three years and six months, seven years and six months, and eleven years and six months after the date of this grant, or within a grace period of six months thereafter upon payment of a surcharge as provided by law. The amount, number of timing of the maintenance fees required may be changed by law or regulation. Unless payment of the applicable maintenance fee is received in the United States Patent and Trademark Office on or before the date the fee is due or within a grace period of six months thereafter, the patent will expire as of the end of such grace period.

US006179807B1

(12) **United States Patent**
Hennigan et al.

(10) **Patent No.: US 6,179,807 B1**
(45) **Date of Patent: Jan. 30, 2001**

(54) **SURGICAL/MEDICAL IRRIGATOR WITH REMOVABLE TIP AND INTEGRATED SUCTION CONDUIT**

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(73) Assignee: **Stryker Corporation**, Kalamazoo, MI (US)

(*) Notice: Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

(21) Appl. No.: **09/425,830**

(22) Filed: **Oct. 22, 1999**

Related U.S. Application Data

(62) Division of application No. 08/915,431, filed on Aug. 20, 1997.

(51) Int. Cl.[7] **A61M 3/02**

(52) U.S. Cl. **604/30**; 604/39

(58) Field of Search 604/35, 39, 43, 604/21, 66, 67, 131, 902, 151

(56) **References Cited**

U.S. PATENT DOCUMENTS

D. 281,935	12/1985	Addleson et al. .
D. 306,146	2/1990	Palmersheim .
4,489,730	12/1984	Hakanig .
4,519,385	5/1985	Addleson et al.
4,595,645	11/1985	Addleson .
4,561,451	12/1985	Addleson .
4,583,531	4/1986	Hamilton .
4,671,631	1/1987	Addleson .
4,681,559	9/1987	Hakanig .
4,692,148	9/1987	Olson .
4,741,678	5/1988	Hakanig .
4,770,648	09/1988	Pratte et al. .
4,941,877	7/1990	Hollo et al. .
4,957,483	9/1990	Clausen et al. .
5,045,056	9/1991	Grubbs et al. .
5,261,750	12/1993	Grubbs et al. .
5,470,301	11/1995	Aasen et al. .
5,484,402	1/1996	Saurer et al. .

OTHER PUBLICATIONS

Zimmer, The Zimmer Vac-A-Pulse Wound Debridement System, Dec., 1986, 2 pgs.

Zimmer, It's a Matter of Time The Pulsavac System, Dec., 1994, 6 pgs.

Zimmer, Pulsavac Wound Debridement System for Power and Control, Dec., 1994, 8 pgs.

Davol, *To Pulsed Lavage*, The Choice Is Remarkably Simple, Jan., 1995, 4 pgs.

Davol, *Performance Irrigation™ Systems*, Pulsed Lavage for Wound Management, Dec., 1995, 2 pgs.

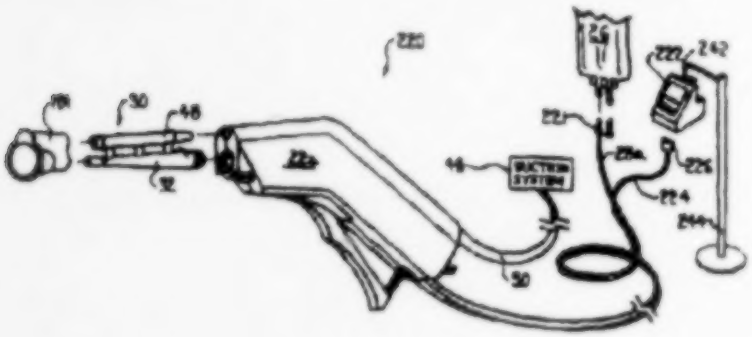
Davol, *To Pulsed Lavage*, The Choice Is Simple, Sep., 1994, 3 pgs.

Primary Examiner—John D. Yasko
(74) *Attorney, Agent, or Firm*—Hyman, Thrift, Bennett & Timm, PC

(57) **ABSTRACT**

An irrigator (30) useful for surgical and medical procedures. The irrigator includes a handpiece (22) to which a tip assembly (30) is attached. The handpiece (22) includes a drain tube (48) that extends through the body of the handpiece and outside of the handpiece to the complementary suction system. The tip assembly includes a discharge tube (32) that is snap mounted into the front of the handpiece and a suction tube (48) that mates to the open front end of the drain tube. A removable splash shield (50) is attached to the front end of the tip assembly. A trigger (44) allows one-handed control of, the position of the handpiece, the on/off state of the irrigator and the rate at which fluid is discharged from the irrigator. A rechargeable power pack (222) can be used to supply the energization current needed to activate a number of different handpieces at different speeds.

34 Claims, 15 Drawing Sheets



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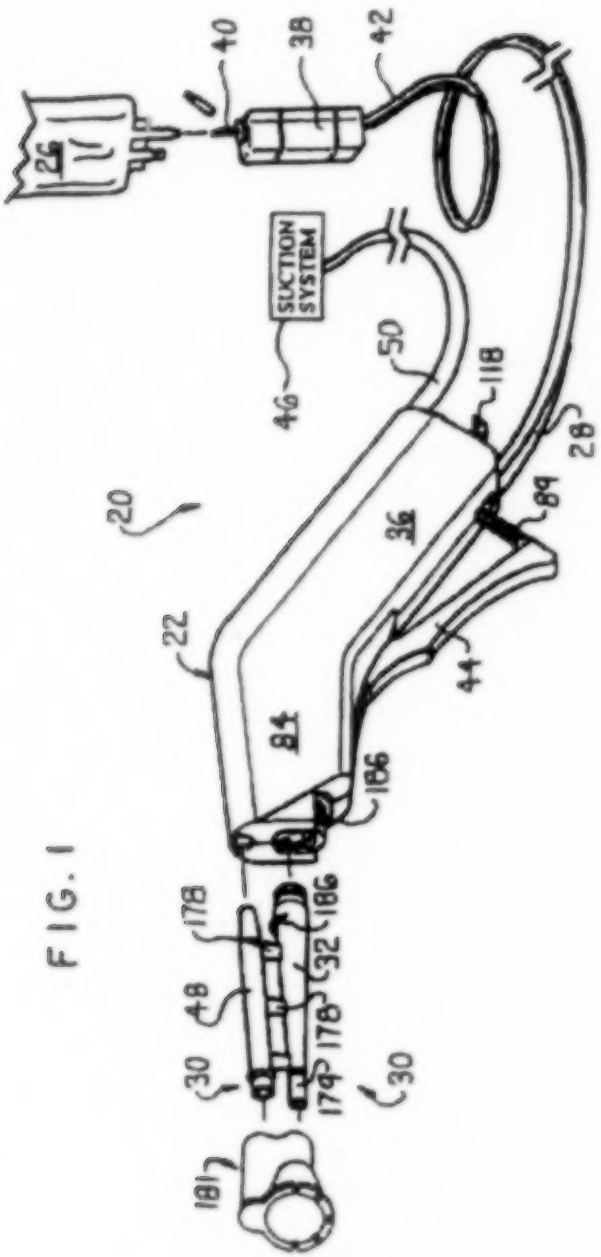

FIG. 1

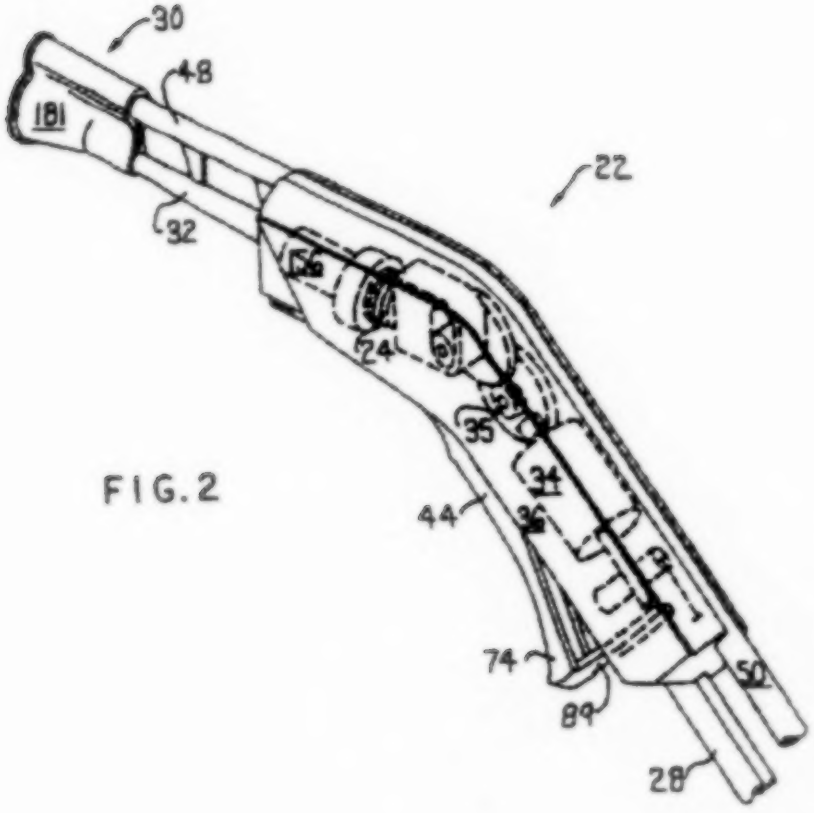

FIG. 2

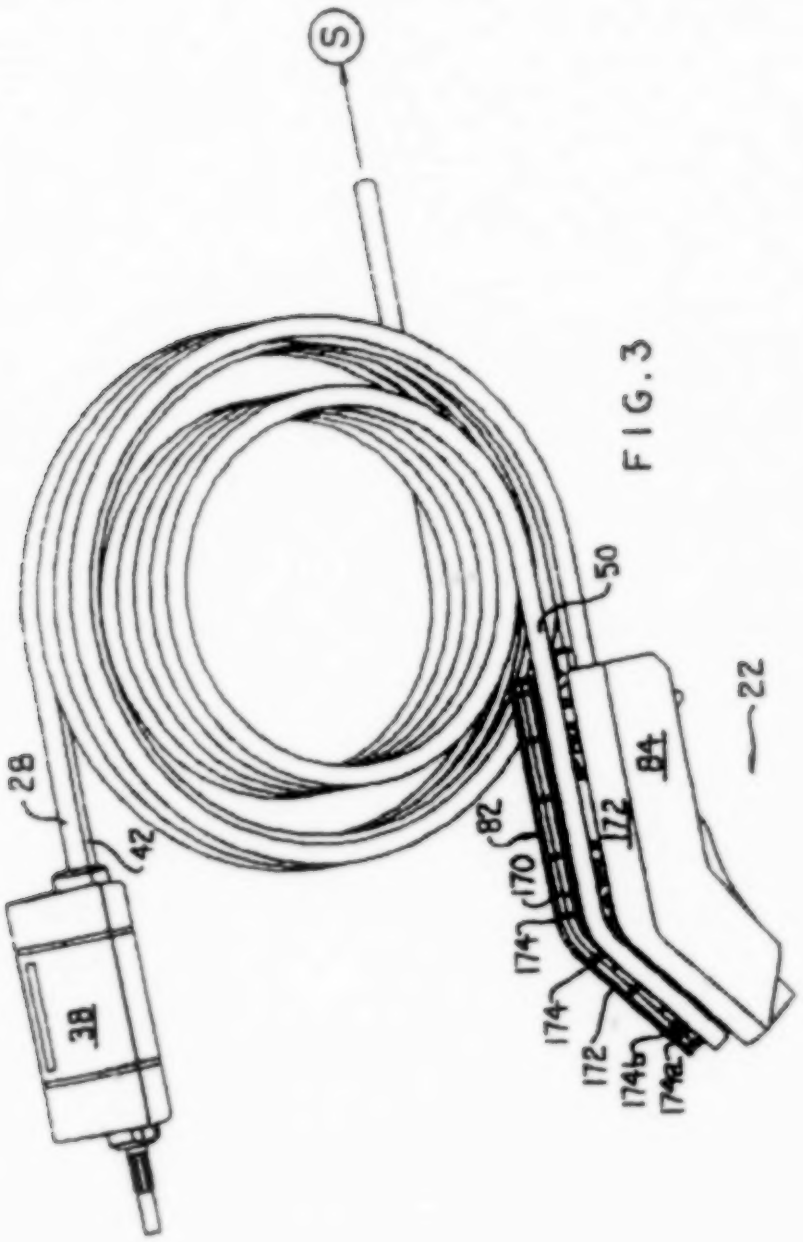

FIG. 3

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FIG. 4

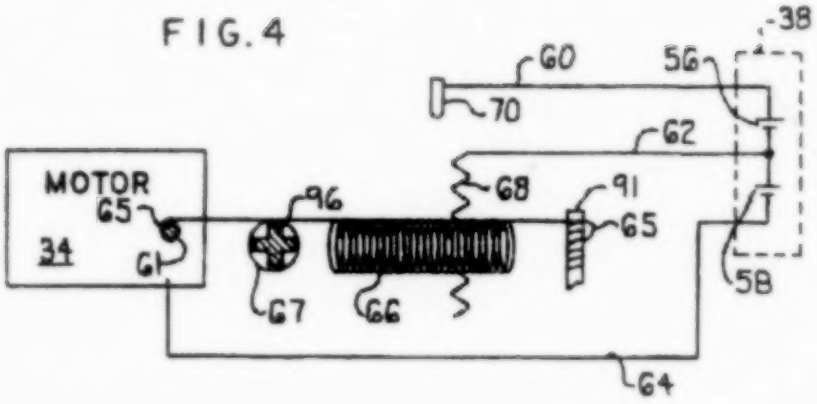
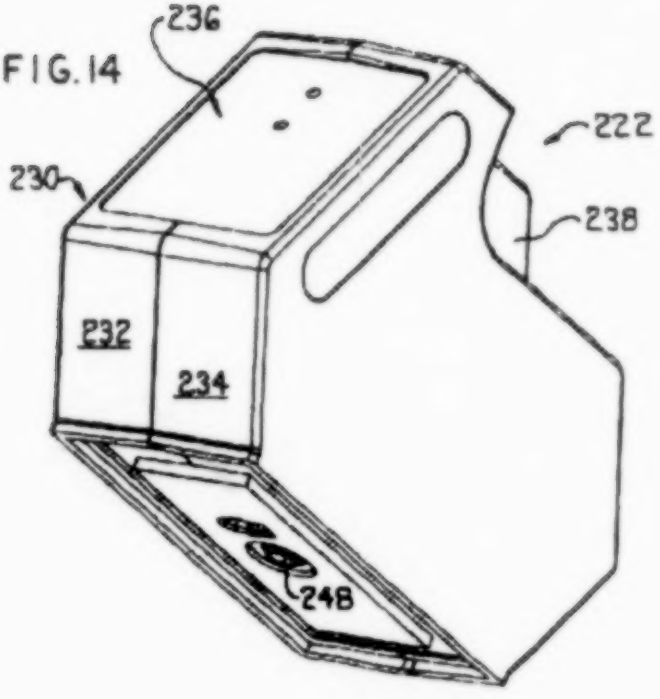


FIG. 14



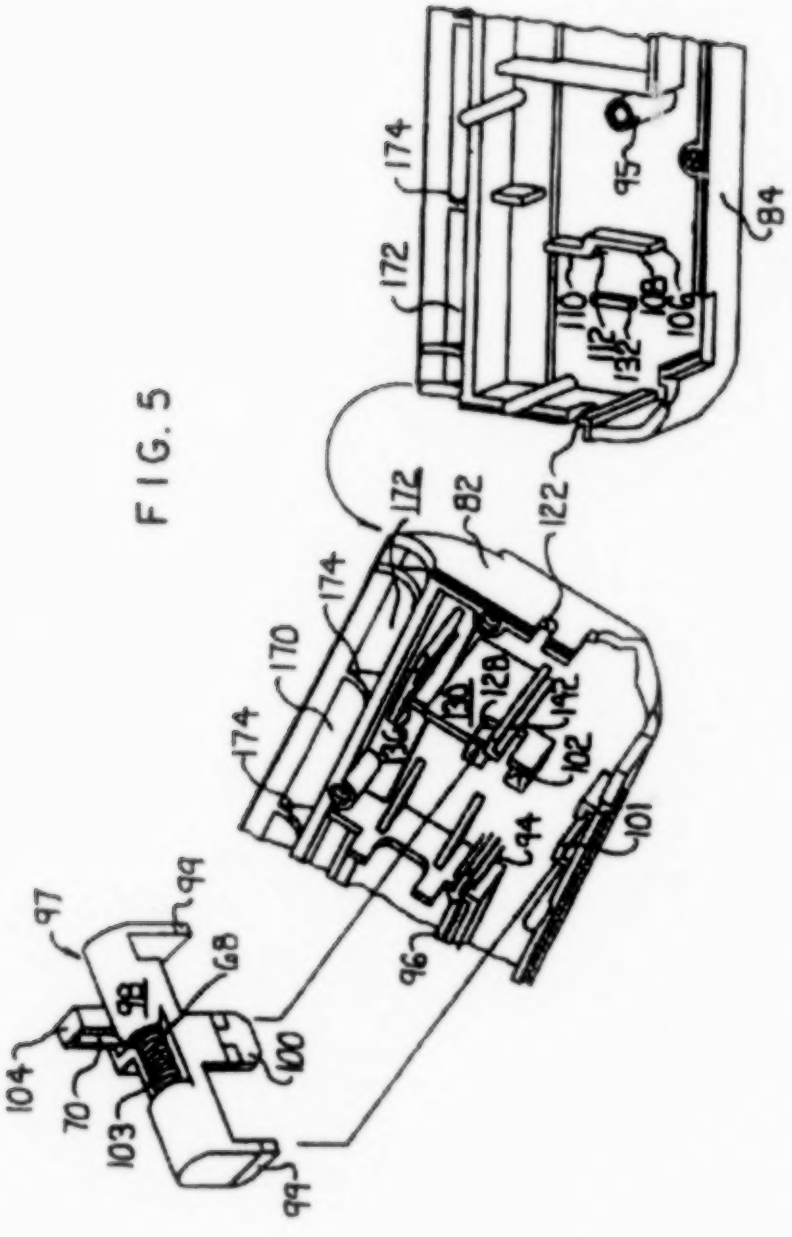

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FIG. 5

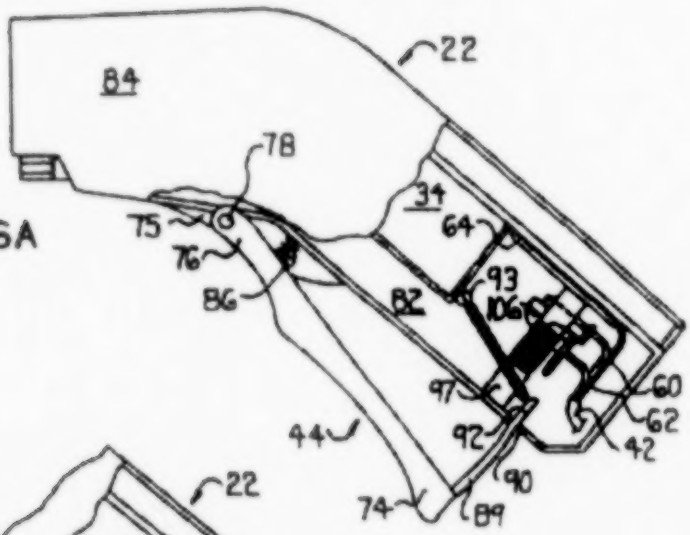


FIG. 6A

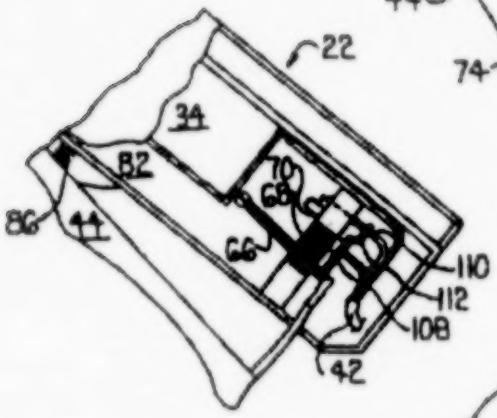


FIG. 6B

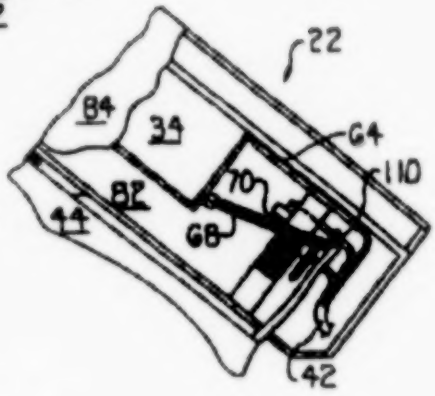


FIG. 6C

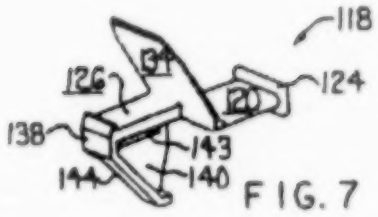


FIG. 7

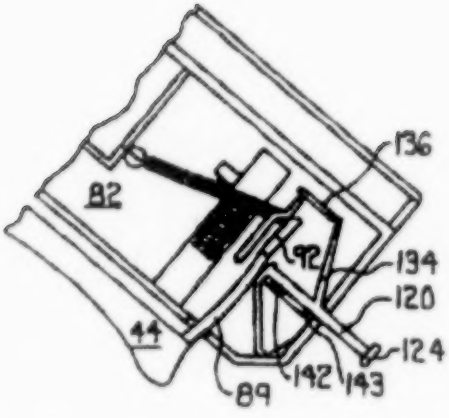


FIG. 7A

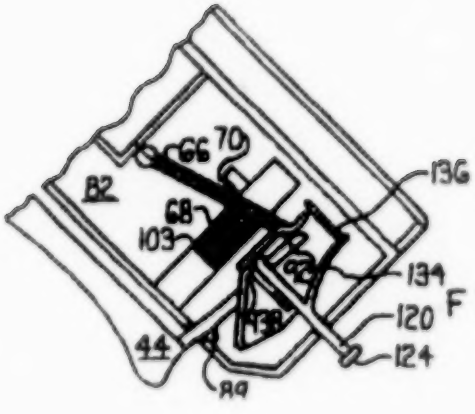


FIG. 7B

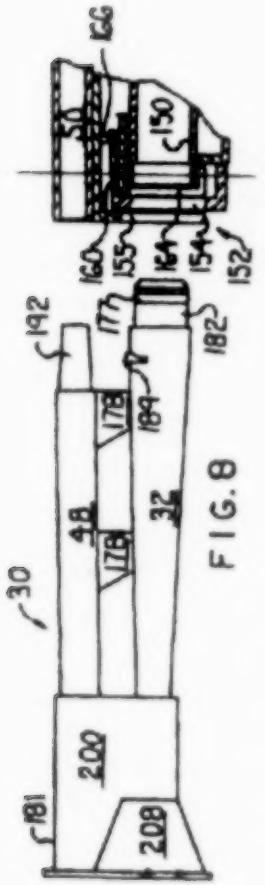


FIG. 8

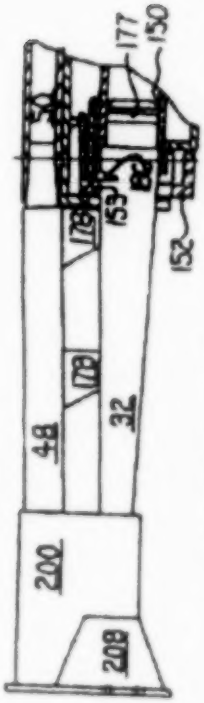


FIG. 11

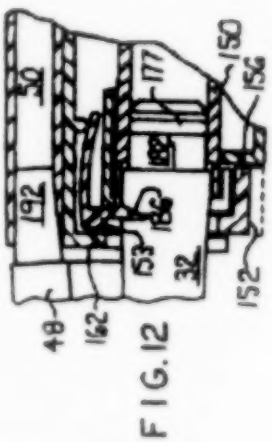


FIG. 12

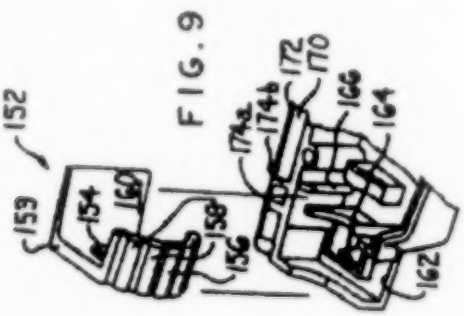
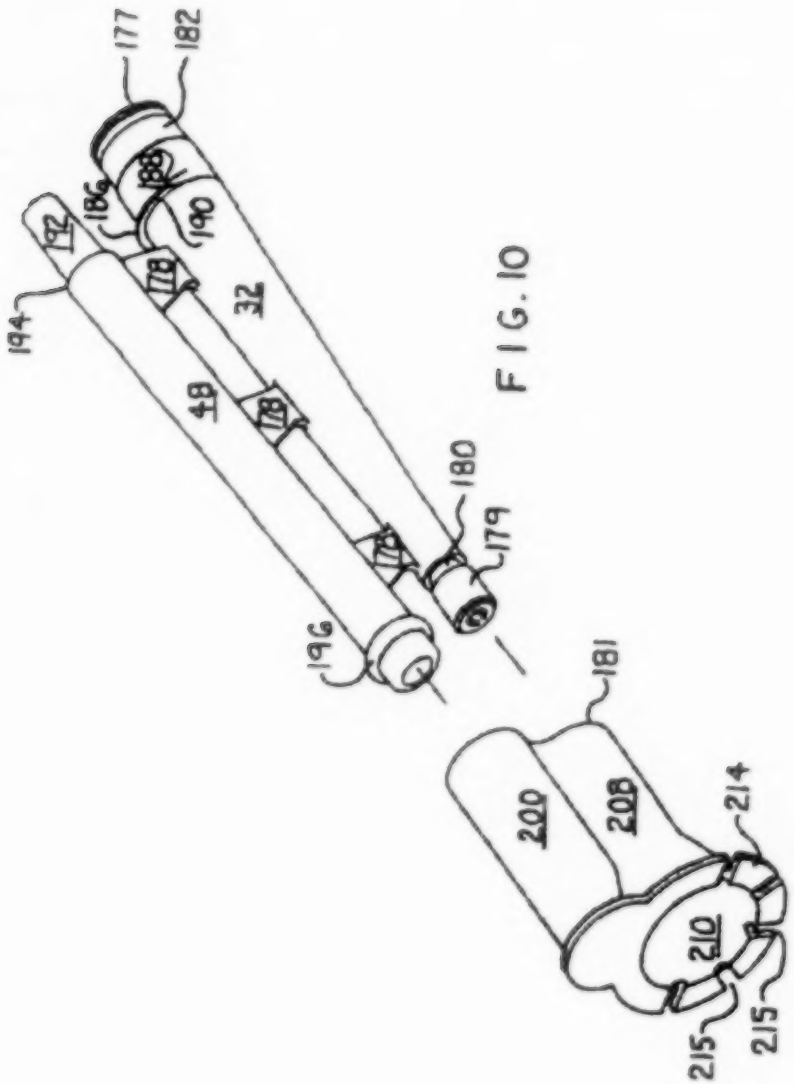


FIG. 9


177
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215

FIG. 10

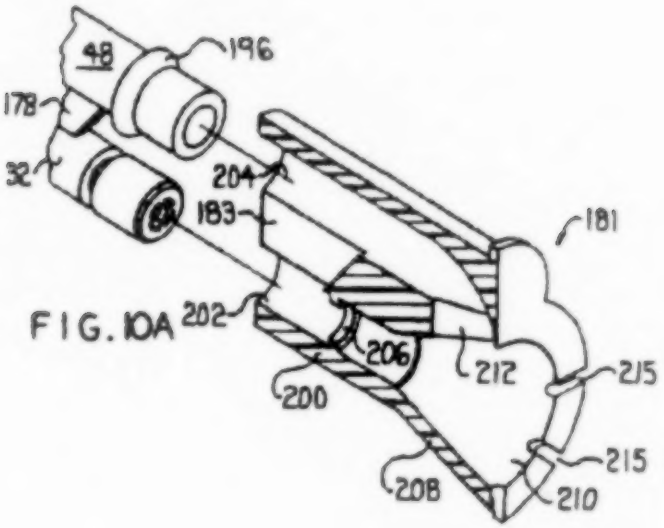


FIG. 10A

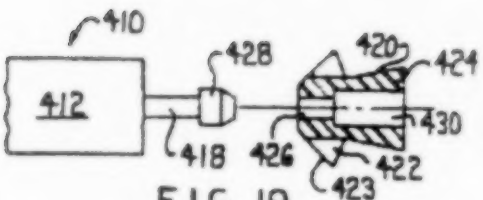


FIG. 19

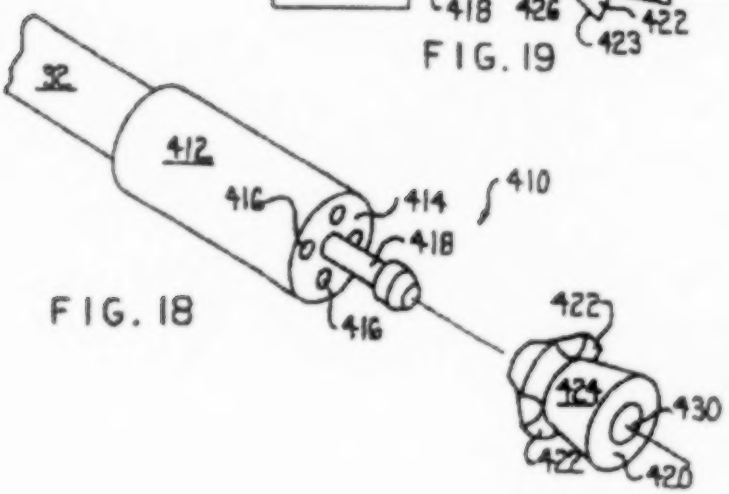


FIG. 18

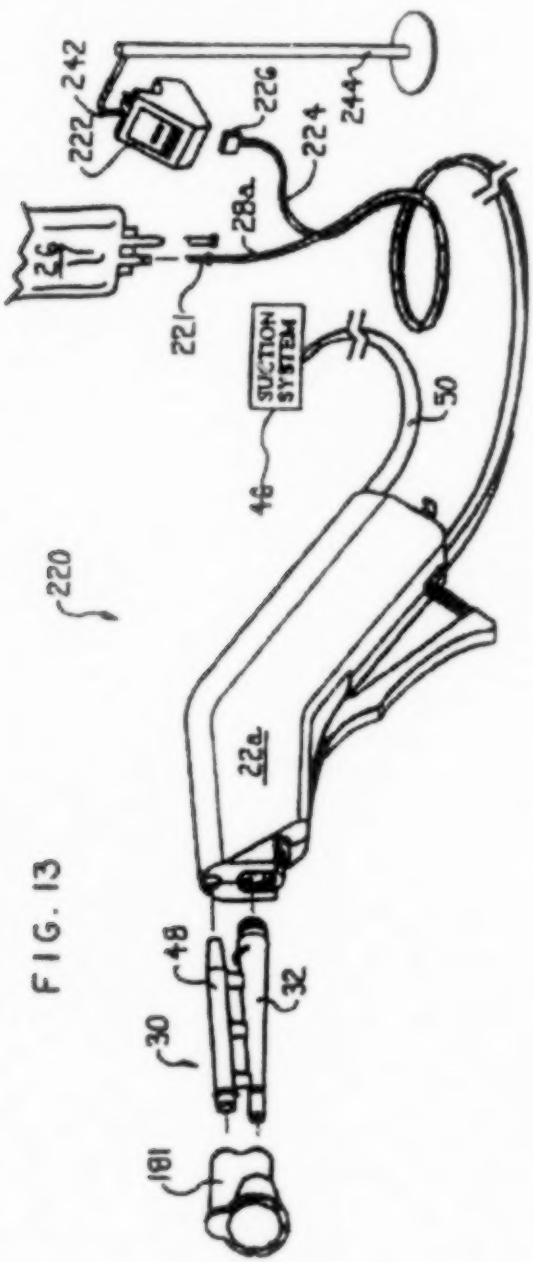

242
222
226
224
244
28a
26
221
SUCTION SYSTEM
50
46
220
22a
48
32
30
181

FIG. 13

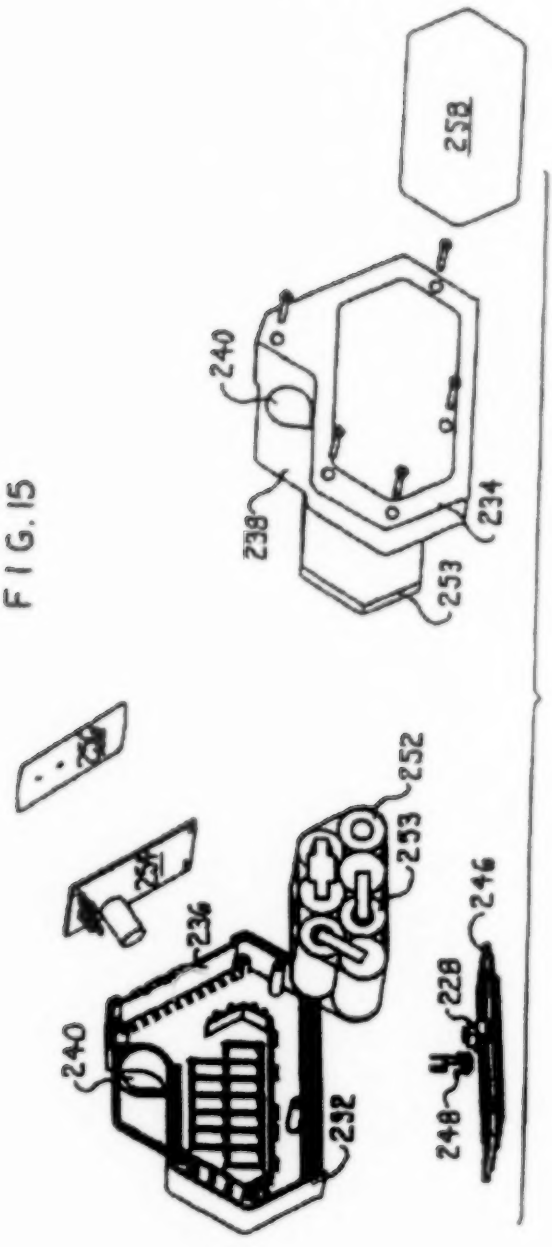


FIG. 15

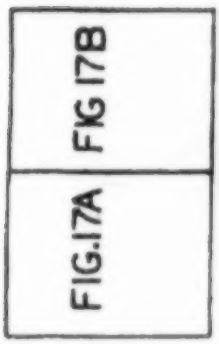


FIG.17A
FIG 17B

FIG.17

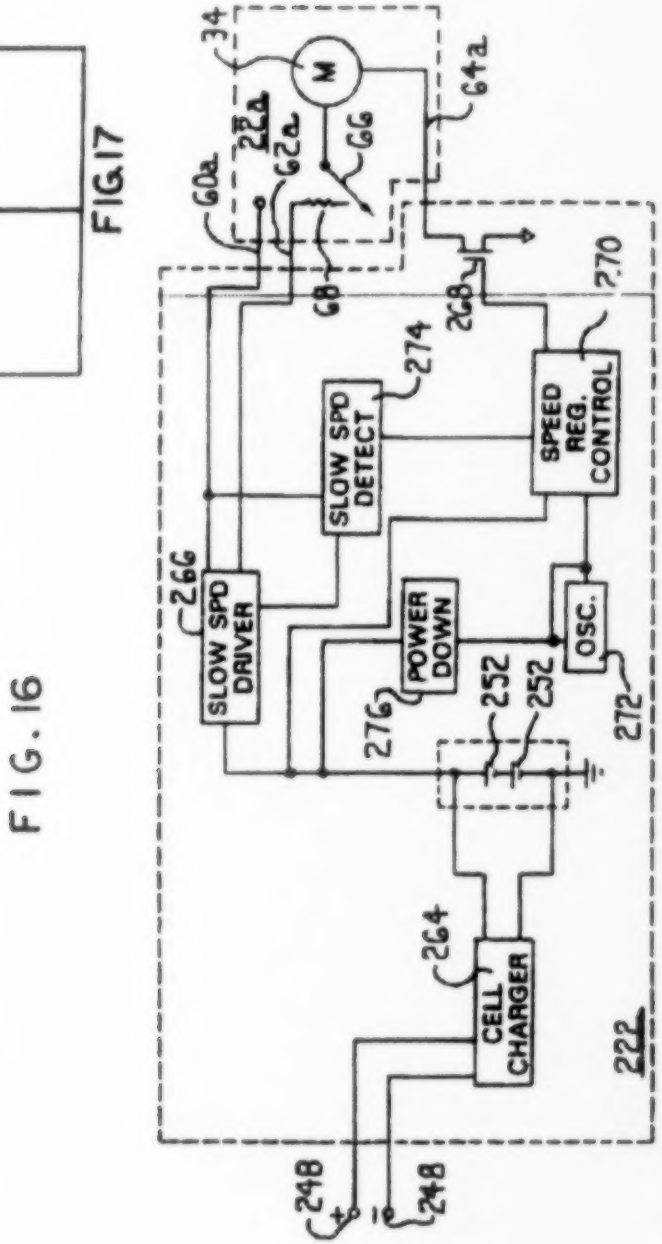
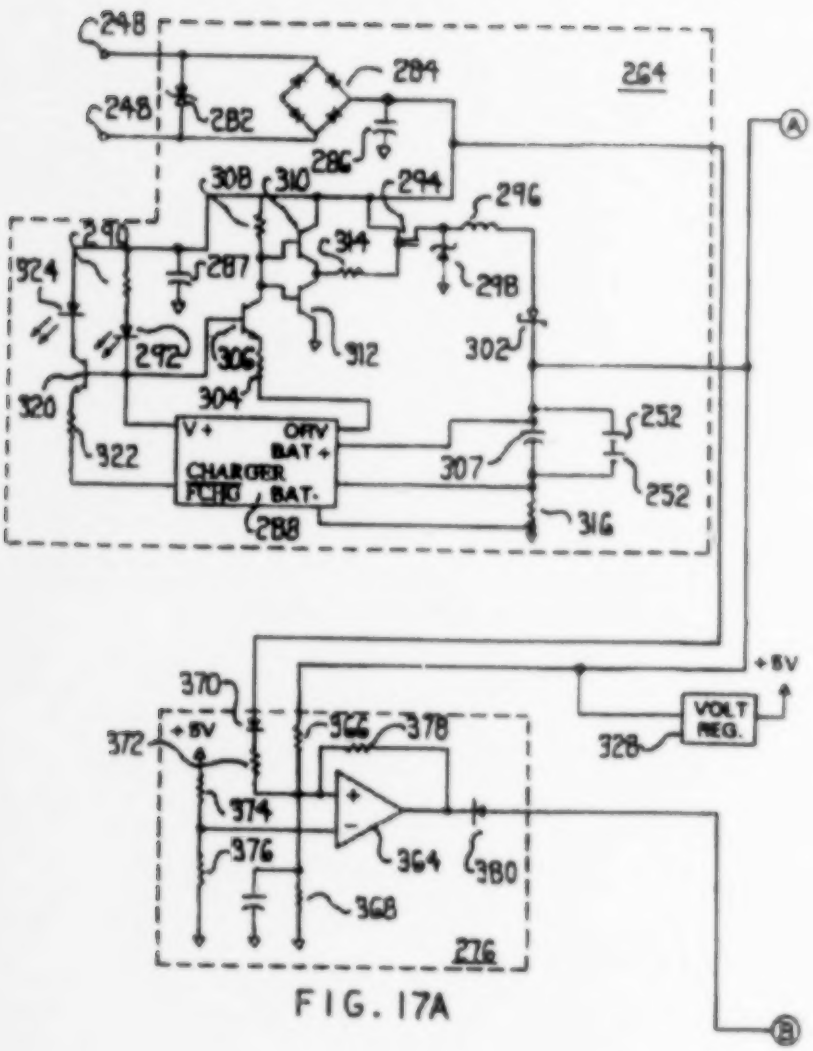

34
M
64a
22a
62a
66
60a
68
268
270
274
SLOW SPD DETECT
SPEED REG. CONTROL
266
SLOW SPD DRIVER
POWER DOWN
OSC.
276
252
252
272
264
CELL CHARGER
222
248
248

FIG. 16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282
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264
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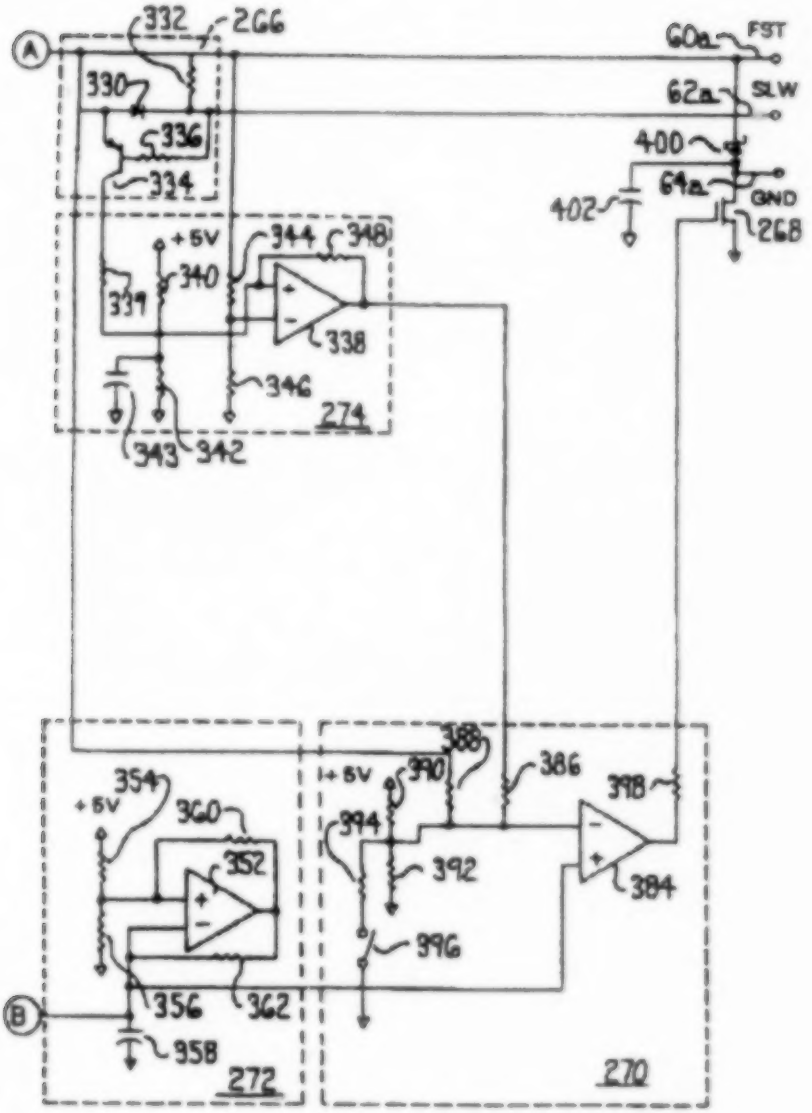
308
310
294
296
290
314
287
298
324
292
306
312
302
320
304
322
V+
OFF
BAT+
CHARGER
FCHG
BAT-
307
252
252
288
316
A
+5V
370
372
+5V
326
378
VOLT REG.
328
374
376
364
380
368
276
B

FIG. 17A


A
332
266
330
336
334
60a
FST
62a
SLW
400
64a
GND
402
268
+5V
344
348
340
339
338
346
274
343
342
B
354
+5V
360
352
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362
958
272
388
390
386
398
394
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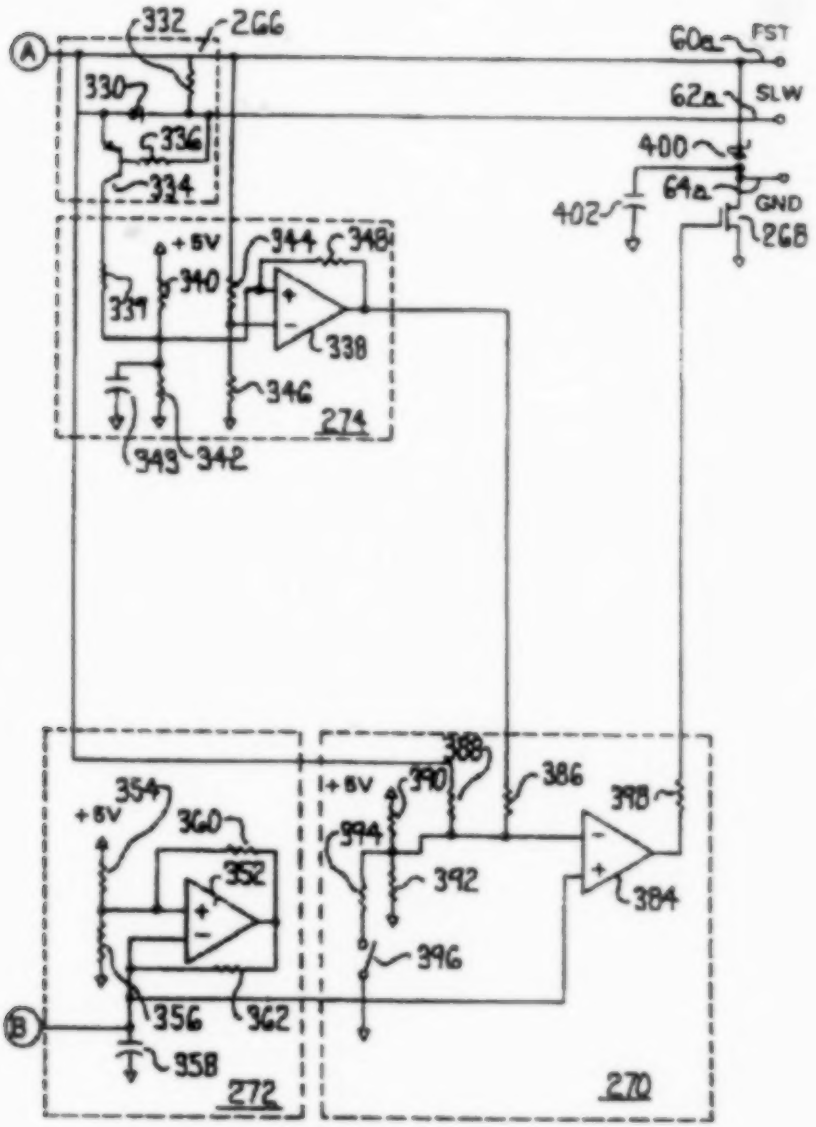
384
396
270

FIG. 17B


A
332
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330
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+5V
340
339
344
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338
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274
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342
60a
FST
62a
SLW
400
64a
GND
402
268
B
354
+5V
360
352
356
362
358
272
388
390
386
398
394
392
384
396
270

FIG. 17B

SURGICAL/MEDICAL IRRIGATOR WITH REMOVABLE TIP AND INTEGRATED SUCTION CONDUIT

This is a division of Ser. No. 08/915,431, filed Aug. 20,1997 pending.

FIELD OF THE INVENTION

This invention relates generally to an irrigator useful for surgical and medical procedures and, more particularly, to an irrigation handpiece to which complementary tips can be readily coupled.

BACKGROUND OF THE INVENTION

In many surgical and medical procedures, an irrigator is employed to deliver pulses of fluid to a particular location on or in the body of a person receiving medical attention. For example, during orthopedic surgery, an irrigator may be employed to deliver pressurized pulses of water or saline solution to an exposed surface of the bone in order to clean the bone. There are also some non-surgical procedures performed which likewise make it desirable to apply pulses of water to a specific site on an individual's skin. Thus, if an individual is suffering from some type of bed sore or some other type of skin wound, it is a common practice to use an irrigator to clean the wound prior to applying a dressing to the wound.

A common type of medical/surgical irrigator includes a handpiece to which a tip assembly is selectively attached. Often, inside the handpiece is a small pump that periodically delivers a quantity of pressurized fluid. Alternatively, the pressurized fluid is delivered to the handpiece from an external pump. The fluid is discharged through a discharge tube integral

with the tip assembly to the selected site on or in the patient. These irrigators deliver fluid in pressurized pulses for two reasons. One reason is that fluid pulses quickly strike the site to which they are applied and leave the site; this action serves to foster the desirable removal of debris from the site. Secondly, the discrete fluid pulses do not obstruct the view of the site as much as it can be obstructed when exposed to a continuous flow of pressurized fluid.

Most irrigator handpieces, in addition to having a conduit through which the sterile fluid is discharged, have a conduit through which the discharged fluid is removed from the site to which it is applied. Typically the fluid is initially withdrawn from the site through a suction tube, also part of the tip assembly. The fluid, as well as any debris in the fluid stream, then flow through a conduit integral with the handpiece. The handpiece suction conduit is connected to a second suction tube that is connected to a suction system separate from the irrigator. Thus, given their ability to essentially simultaneously clean a site on a patient and remove the debris generated by the cleaning process it should be readily apparent why irrigators have become useful tools for facilitating many medical and surgical procedures.

There are, however, some disadvantages associated with current surgical irrigators. One particular disadvantage associated with some known irrigators is how the tip assembly is connected to the handpiece. When these components are coupled together there should be two leakproof seals: a first seal between the handpiece and the discharge tube through which the irrigating fluid is discharged; and a second seal between the suction tube and the complementary hand-

piece conduit. Some tip assemblies sometimes do not properly mate with their complementary handpieces so as to result in a leaks. Leakage around a tip assembly suction tube-handpiece joint is especially prone to occur when the tip assembly is exposed to side loading. This side loading occurs when the tip assembly is pressed against tissue and flexes relative to the handpiece.

Still another problem associated with some irrigators is that the suction conduits integral to the handpieces occasionally clog. This clogging occurs because the material drawn away from the site to which the irrigator is applied is often in solid or semi-sold form. Sometimes, especially if this material is relatively large in size, the material will clog the suction conduit in the handpiece so as to significantly reduce the utility of the irrigator.

Moreover, it is desirable to provide medical personnel with some ability to control the rate at which irrigation fluid is discharged from the handpiece. Some handpieces are provided with stepped switches that are incrementally set in order to establish the voltage of the power signal applied to the motor so as to, in turn, set pump speed. One disadvantage of some known handpieces is that these switches are located in positions wherein, with a single hand, it is difficult, if not impossible, to both direct the handpiece and regulate the discharge of irrigating fluid.

Moreover, it also desirable to provide some means for controlling the pattern of the irrigating fluid discharged from the irrigator. To date, one of the more common practices is to simply provide the personnel using the irrigator with a number of different tip as-

semblies, each with its own nozzle, that causes the irrigating fluid to be discharged in a specific spray pattern. A disadvantage of this practice is that it increases the number of different tips that a medical facility is required to keep in inventory. Still another disadvantage of this practice is that if, during a procedure, a change in fluid flow patterns is desired the medical personnel must spend time switching tips.

Also, while it is common practice to provide handpieces with use-once, disposable battery packs, there are some circumstances when it may be more economical to provide a rechargeable power pack for repeatedly energizing different handpieces.

SUMMARY OF THE INVENTION

This invention relates to a new irrigator for medical and surgical procedures with a tip assembly readily seals to the complementary handpiece, and a handpiece with a suction conduit that is not prone to clogging and a switch that allows easy control of pump speed. This invention also relates to a tip assembly for a handpiece with a nozzle that allows one to set the spray pattern of the fluid delivered by the nozzle. This invention further relates to a new irrigator with a rechargeable power pack that can provide drive signals of different potentials to the handpiece and that, even after being after discharged numerous times, can be fully recharged.

BRIEF DESCRIPTION OF THE DRAWINGS

This invention is defined with particularity in the appended claims. The advantages of the invention may be better understood by referring to the following detailed description, in which:

FIG. 1 depicts the basic components of an irrigator of this invention;

FIG. 2 is a view of the handpiece of the irrigator that illustrates the basic components internal to the handpiece;

FIG. 3 is a perspective view illustrating the relationship of the drain tube to the handpiece;

FIG. 4 is a schematic and diagrammatic illustration of the components of the irrigator that regulate the on/off state of the irrigator as well as flow and the rate at which fluid is discharged from the irrigator.

FIG. 5 is an exploded view of some of the components internal to the handpiece that regulate the speed of the pump;

FIGS. 6A, 6B and 6C are side views illustrating the different positions of the components that regulate pump speed, depicting, respectively, their position when the irrigator is off, operated at low speed, and operated at high speed;

FIG. 7 illustrates the trigger lock employed to lock the irrigator into its high speed operating state;

FIGS. 7A and 7B illustrate how the trigger lock cooperates with the other components internal to the handpiece that lock the irrigator into its high speed operating state;

FIG. 8 is a side, partial cross-sectional view depicting how the tip assembly is inserted in the handpiece;

FIG. 9 is a perspective view of the tip lock internal to the handpiece;

FIG. 10 is a view depicting the basic components of the removable tip assembly including the detachable spray shield;

FIG. 10A is an enlarged view of the front end of the tip assembly depicting the removable shield in a cross-sectional view;

FIG. 11 is a partial cross sectional view illustrating how the tip assembly is locked into the front end of the handpiece;

FIG. 12 is a side, partial cross-sectional view depicting how the tip lock depressed to allow the removal of the tip assembly from the handpiece;

FIG. 13 is a view of an alternative irrigator of this invention wherein the handpiece is powered by a rechargeable battery pack;

FIG. 14 is an isometric, upwardly oriented view of the rechargeable battery pack;

FIG. 15 is an exploded view of the components internal to the rechargeable battery pack;

FIG. 16 is a block diagram of the electronic circuitry internal to the battery pack for both controlling the charging of the cells therein and their discharge by the handpiece;

FIG. 17 is an assembly drawing illustrating how FIGS. 17A and 17B are assembled together to form a

schematic diagram of the electronic circuitry of FIG. 16;

FIG. 18 is a view of a nozzle assembly that may be fitted to the forward end of the discharge tube of a tip assembly of the irrigator of this invention; and

FIG. 19 is a cross sectional view of the rotating head of the nozzle assembly of FIG. 18.

DETAILED DESCRIPTION

FIGS. 1 and 2 illustrate a basic irrigator 20 of this invention. Irrigator 20 includes a handpiece 22 with a pump 24 that discharges pulses of fluid to a specific site on or in the body of the patient. The fluid is stored in a bag 26 and is gravity feed or suction drawn into the handpiece through a supply tube 28. The fluid is discharged from the front end of the handpiece 22 through a removable tip assembly 30. More particularly, tip assembly 30 has a discharge tube 32 in fluid communication with the pump 24 that is directed to the desired discharge site. The mechanical force for actuating the pump 24 comes from a motor 34. Mechanically, the rotational force developed by motor 34 is provided to pump 24 through a gear train 35. The motor 34 is mounted a lower section of the handpiece 22 hereinafter referred to as the handgrip 36.

Current for energizing the motor 34 is supplied by battery pack 38. In the depicted version of the invention, battery pack 38 is provided with a spike 40, for establishing a fluid communication path to the bag 26. The end of supply tube 28 is disposed in battery pack 38 and is connected to the base end of the spike 40, A power cord 42 extends between the battery pack 38 and the handpiece 22 for supplying the energization

current to the handpiece. The power cord 42 is shown as being adhesively secured to the outside of supply tube 28. A lever-like trigger 44 attached to the undersurface of the handgrip 36 is depressed to control the on/off state of the motor 34 and motor speed.

Irrigator 20 also presents a suction head to the discharge site so that the discharged fluid and any debris therein can be removed. The force for this suction head comes from a suction system 46 separate from the irrigator 20 and not part of this invention. The suction head is presented to the discharge site through the open end of a rigid suction tube 48 integral with tip assembly 30. Suction tube 48 is placed in fluid communication with suction system 46 through a flexible drain tube 50 that is mounted in the handpiece 22 and extends from the handpiece as a single tube so that it can be coupled to an inlet port, (not illustrated,) integral with the suction system 46.

The control of the drive signal applied to motor 34 to regulate both the on/off state of the irrigator and the rate of fluid discharge is now explained by initial reference to FIG. 4. It should be understood that internal to the battery pack 38 are two series connected cells 56 and 58. In some preferred versions of the invention, each cell 56 and 58 actually consists of four series-connected AA batteries. A circuit for supplying the energization current to the motor 34 is established by one of two power conductors 60 or 62 and a ground conductor 64 connected to the negative terminal of cell 58. Power conductor 60 is shown as being connected to the positive terminal of cell 56. Consequently, the potential across conductors 60 and 64 is the full potential developed across cells 56 and 58. Power conductor 62 is connected to the junction of cells 56 and

58; the potential across conductors 62 and 64 is just the potential developed by cell 58. Conductors 60, 62 and 64 are the conductors internal to power cord 42.

A movable spring 66 serves as the wiper that ties either conductor 60 or 62 to motor 34 to regulate the application of the energization voltage to the motor. One end of spring 66 is connected to a terminal 61 internal to motor 34 to which the positive potential is applied. Spring 66 has a first position wherein it is not connected to either conductor 60 or 62; this is the off position for the irrigator 20. When actuation of the irrigator 20 is desired, spring 66 is moved to a second position in which it is contact with the resistive wire of a wire-wound resistor 68 that is series-connected to conductor 62. In one version of the invention, resistor 68 is a 3 Ohm resistor. Resistor 68 serves as a variable load to regulate the fraction of the potential developed by cell 58 that is applied to the motor 34 When spring 66 is positioned across the full length of the resistor 68, there is the largest voltage drop across the resistor 68. Therefore, a relatively small voltage is applied to the motor 34. The motor 34 and, in turn, pump 24, operate at a relatively slow speed so as to result in the relatively slow discharge of fluid by the irrigator. When faster operation of the irrigator 20 is desired, spring 66 is repositioned along the length of resistor 68 to reduce the voltage drop across the resistor and increase the voltage applied to the motor 34.

When operation of the irrigator 20 at still higher speed is desired, spring 66 is reset to a third position wherein it is spaced from resistor 68 and abuts a fixed contact 70. Contact 70 is connected to the end of conductor 60. Consequently, when spring 66 abuts con-

tact 70, the full potential developed across cells 56 and 58, a high speed drive signal, is applied to motor 34 so as to result in the highest speed operation of the irrigator 20.

Spring 66 is from a conductive material such as plated beryllium copper. The position of spring 66 is set by the selective movement of trigger 44, now discussed by reference to FIGS. 5 and 6A. More particularly, trigger 44 is shaped to have an elongated body 74 located along the lower, downward facing surface of handgrip 36. A finger 76 extends forward from the front end of trigger body 74. Opposed pins 78, (one shown,) extend laterally away from the sides of finger 76 seat in openings, (not depicted) formed in webs 75 integral with the right and left shells 82 and 84, respectively that form the body of handpiece 22. Pins 78 thus pivotally secure trigger 44 to the handpiece 22. A coil spring 86 located between a portion of the body 74 adjacent finger 76 and the opposed surface of the handpiece 22 normally biases trigger 44 so that its body 74 is positioned away from the adjacent lower surface of handgrip 36. When trigger 44 is so positioned, spring 66 is spaced from both resistor 68 and contact 70 so as to place the irrigator 20 in the off state.

Trigger 44 is further formed to have a single leg 89 that extends from the end of the main body 74 distal from finger 76 into the handpiece 22. Shells 82 and 84 are formed to define a slot 90 spaced forward of the rear ends of the handpiece through which leg 89 extends. In the illustrated version of the invention, leg 89 has an arcuate profile centered around the axis of pins 78. A foot 92 is attached to the end of leg 89 seat-

ed inside handpiece 22. Foot 92 is greater in width than leg 89.

Returning to FIG. 4 it can be seen that the opposed ends of spring 66 are provided with hooks 65 to facilitate the securement of the spring to the motor 34. Spring 66 is formed with a loop 67 that extends around a post 93 adjacent motor 34 to foot 92 of the trigger 44. Post 93 is actually formed from a first, male post 94 integral with right shell 82 and a female post 95 integral with left shell 84. Loop 67 is fitted over a reduced diameter boss 96 integral with male post 94 that seats in female post 95. The hook 65 integral with spring 66 adjacent loop 67 is secured to the terminal 61 internal to motor 34. The opposed hook 65 is fitted around slots 91, (one slot illustrated,) formed in foot 92 of the trigger 44. When this spring 66 is so positioned, it extends across a non-conductive resistor support 97 secured inside the right shell 82, best seen in FIGS. 5 and 6A. Resistor support 97 has an elongated sleeve-like main casing 98 in which resistor 68 is seated. Tabs 99 extend perpendicular away from the longitudinal axis of main casing 98 at the ends of the casing. A third tab 100 extends from the center of main casing towards the right shell 82. Lower tab 99 and center-located tab 100 seat in complementary sockets 101 and 102, respectively, formed in right shell 82 to hold resistor support 97 in position. The upper tab 99 simply abuts the inside wall of right shell 82 to provide mechanical support for the resistor support 97.

Main casing 98 is formed with a window 103 which exposes the wire coil of resistor 68. Resistor support 97 further includes a three-sided mounting bracket 104 which is integral with main casing 98. Mounting

bracket 104 is shaped to hold fixed contact 70 which is shaped as U-shaped piece of conductive metal that is compression-secured in the mounting bracket.

The position of spring 66 relative to resistor support 97 is a function of the extent to which trigger 44 is depressed. When trigger 44 is not depressed, spring 66 is located against the lower portion of the main casing 98 so as to be spaced away from both window 103 and fixed contact 70 as seen in FIG. 6A. This is the position of the spring 66 when irrigator 20 is in the off state. When low speed operation of the irrigator 20 is desired, trigger 44 is partially depressed to position spring 66; across window 103, depicted by FIG. 6B. When the spring 66 is so positioned, it abuts resistor 68 so as to allow a low voltage drive signal to be applied to motor 34. By controlling the depression of the trigger 44, the extent to which resistor 68 is placed in series with conductor 62 is controlled. This positioning allows the low speed discharge of the irrigator 20 to be selectively set over a range of operating speeds.

When operation of the irrigator at high speed is desired, trigger 44 is fully depressed. The complete depression of the trigger 44 pivots spring 66 away from resistor 68 and against fixed contact 70, as seen by FIG. 6C. Once the spring 66 and contact 70 abut, the full potential across cells 56 and 58 is applied to the motor 34 so as to cause the irrigator 20 to run at its highest speed.

It will further be observed from FIG. 5 and 6A that left shell 84 is formed with a stepped rib 106 that projects into a space inside the handpiece 22 adjacent the foot 92 of trigger 44. More particularly, rib 106 ex-

tends generally perpendicularly relative to the longitudinal axis of the handgrip 36 portion of handpiece 22. Rib 106 is shaped to have a first, lower portion 108 and a second, upper portion 110 located slightly forward of lower portion 108. An angled step 112 in rib 106 serves as the transition section between the lower and upper sections 108 and 110, respectively.

When trigger 44 is depressed to operate the irrigator 20, the forward facing surface of foot 92 presses against the rearward facing surface of rib 106. When the trigger 44 is initially depressed, operated in the low speed state, foot 92 rides against the lower portion 108 of rib 106 as seen in FIG. 6B. Further depression of trigger 44 results in foot 92 seating in the space defined by step 112. If higher speed operation of irrigator 20 is desired, further depression of trigger 44 forces foot 92 out of step 112 and against the surface of upper section 110 of the rib 106. This movement of the trigger causes spring 66 to abut contact 70.

The seating of the foot 92 of trigger 44 against step 112 performs two functions. First, it holds the trigger 44 so that spring 66 is positioned so that there is a minimum voltage drop across resistor 68 and the spring will be spaced away from fixed contact. 70. Thus, the trigger 44 and spring 66 are set to cause the highest possible low speed drive signal to be applied to the motor 34. Secondly, the seating of trigger 44 provides a tactile indication to the person using the irrigator 20 that continued depression of the trigger 44 will cause the irrigator to transition from the low speed operating state to the high speed operating state.

Handpiece 22 further includes a trigger lock 118, now described by reference to FIGS. 5, 7 and 7A, that holds trigger 44 in the fully depressed/high speed operating position. Trigger lock 118 has a flat, rectangularly shaped base 120 that extends into the handpiece 22 through a slot 122 formed rear end of the handpiece. A foot 124 extends perpendicularly across the rear end of base 120 to provide a surface against which an individual can place his/her finger. Extending forward from base 120, trigger lock 118 has a neck 126. Neck 126, while coplanar with base 120, is partially offset to one side of the base. The neck 126 is seated in an opening 128 defined in a flange 130 that extends into the center of the handpiece from right shell 82. Opening 128 is closed by a smaller flange 132 integral with left shell 84 that is aligned with flange 130.

Trigger lock 118 is further formed with a flexible, cantilever spring arm 134 that extends upwards and forwardly from the interface between base 120 and neck 126. In order to facilitate the flexible nature of spring arm 134, trigger lock 118 is formed so that spring arm is relatively thin in comparison to the thickness of base 120 and neck 126. For example, in one version of the invention, trigger lock 118 is formed from high impact polystyrene plastic, base 120 and neck 126 have a thickness of approximately 0.080 inches and spring arm 134 has a thickness of approximately 0.014 inches. The upper edge of spring arm 134 abuts a horizontally extending flange 136 that extends into the center of the handpiece from right shell 82. Owing to the flexible nature of spring arm 134, when trigger lock 118 is pressed forward, the action of the spring arm 134 abutting flange 136 places a rearward-acting force on the trigger lock.

The trigger lock **118** further includes a head **138** that is located adjacent the forward end of neck **126**. Head **138** extends perpendicularly across neck **126** to project above the upper surface of the neck. There is also a web **140** that extends downwardly from neck **126**. Web **140** is formed to define a slot **143** immediately below neck **126**. When trigger lock **118** is fitted in handpiece, a lower, horizontally aligned portion **142** of flange **130** extends through slot **143**. This horizontal portion **142** of flange **130** thus provides structural support to hold trigger lock **118** in place. Web **140** itself provides structural rigidity to the neck **126**. In the illustrated version of the invention, a flange **144** extends perpendicularly across the forward edge of web **140**. Flange **140** is integral with head **138**.

After trigger **44** is placed in the high speed operating position, trigger lock **118** is employed to lock it in this position as depicted by FIG. **7B**. The person wanting to so set the irrigator **20**, presses in on the exposed portion of the trigger lock **118** to cause its forward movement. The forward displacement of the trigger lock **118** positions its neck **126** under the foot **92** of the trigger **44**. Downward movement of the trigger **44** upon the release of an actuating grasp is stopped by the trigger lock **118**. Instead, the trigger **44** is locked in position so as to hold spring **66** against contact **70**. Irrigator **20** is unlocked from the high speed operating state by pressing upwardly on the trigger **44**. Once the foot **92** of the trigger **44** clears head **138** of the trigger lock **118**, spring arm **134** exerts sufficient force on the trigger lock **118** to move the trigger lock rearwardly, away from the trigger **44**. The return of the trigger lock **118** to its initial position allows trigger **44** and spring **66** to be returned to their low speed or off operating positions.

As seen in FIGS. 2 and 8, pump 24 has its own sleeve-like, open ended discharge head 150. Pump 24 is seated in the forward end of the handpiece 22 so that discharge head 150 is directed towards the front end of the handpiece and extends out through an opening, (not identified,) defined by shells 82 and 84. A tip lock 152, seen in FIGS. 8 and 9, is positioned in the front of the handpiece 22 immediately forward of pump discharge head 150 for securing the tip assembly 30 to the handpiece. The tip lock 152 is formed from a single piece of flexible plastic such as a high impact polystyrene. Tip lock 152 is shaped to have a flat face plate 153 that is located in front of the open end of the pump discharge head 150. Face plate 153 is provided with an oval opening 154 through which the rear end of the discharge tube 32 is inserted into the discharge head 150. It will be further noted that the portion of face plate 153 that defines opening 154 has a beveled surface 155 around the upper portion of the opening 154. Tip lock 152 further includes an arcuately shaped base plate 156 that extends perpendicularly rearward from face plate 153. In the illustrated version of the invention, base plate 156 is provided with raised members 158 to facilitate manual depression of tip lock 152. A spring plate 160 integrally formed with tip lock 152 extends rearwardly from the top edge of face plate 153. Tip lock 152 is molded so that in its unbiased state, spring plate 160 projects approximately 96° away from face plate 153.

The upper two-thirds of tip lock 152 are seated within opposed L-shaped brackets 162 that extend forward from shells 82 and 84. Brackets 162 form the most forward facial surface of the front end of handpiece 22. The tip lock 152 is held in place by opposed L-shaped three-sided ribs 164 integral with shells 82

and 84. When the handpiece 22 is assembled, ribs 164 block downward movement of the spring plate 160 so as to prevent tip lock 152 from falling out of the handpiece. The base plate 156 is, however, exposed for manual displacement. Shells 82 and 84 are further formed to define a biasing bar 166 that extends across the width of the handpiece 22. Biasing bar 166 is positioned so as to abut the rear end of spring plate 160. Biasing bar 166 is thus the component internal to the handpiece 22 that acts in opposition to spring plate 160 to urge tip lock 152 downwardly.

Drain tube 50, as seen in FIG. 3, is seated in an elongated channel 170 that extends along the top of handpiece 22. Channel 170 is formed by two external spines 172, each spine being integrally formed with a separate one of shells 82 and 84. Each spine 172 extends the length of the shell 82 or 84 above the portion of the shell 82 or 84 that forms the enclosed body of the handpiece 22. In the depicted version of the invention, spines 172 are formed as curved walls. Also integral with shells 82 and 84 are webs 174, seen in FIGS. 3 and 9, that extend from the inner walls of spines 172 to the adjacent outer surfaces of the shells. Webs 174 are formed to have curved outer surfaces that define the circular cross-sectional profile of channel 170. Spines 172 are formed so that the there are pairs of opposed webs 174 integral with the shells 82 and 84 that are in planar alignment. Spines 172 are further dimensioned so that the top surfaces thereof do not abut.

When handpiece 22 is assembled, drain tube 50 is seated between shells 82 and 84 so as to be seated in channel 170. The opposed webs 174 impose a slight inwardly directed force of the drain tube 50 so as to

compress and secure the drain tube 50 to the handpiece. When the tip assembly 30 is coupled to the handpiece 22, suction tube 48 seats in the front end of the drain tube 50. In preferred versions of the invention, shells 82 and 84 are formed so that the two most forward webs, webs 174*a* and 174*b*, are positioned rearwardly away from the portion of the drain tube 50 in which the suction tube 48 is seated. This positioning ensures that, when the tip assembly 30 is coupled to the handpiece 22, the compression force developed by webs 174*a* and 174*b* holds drain tube 50 in place.

FIGS. 1 and 10 illustrate the basic components tip assembly 30. The discharge tube 32 and the suction tube 48 are connected to each other by a set of spaced apart webs 178. A nozzle 179 is fitted over the open forward end of the discharge tube 32 to direct the stream of fluid discharged therefrom. It will be rioted that the nozzle 179 is constructed to define an annular groove 180 around the front end of the discharge tube 32. A splash shield 181 is removably fitted over the open ends of the depicted tube assembly. The rear end of the discharge tube 32, the end that is fitted into the handpiece 22, is provided with a neck 182 that has a reduced outer diameter in comparison to the immediately adjacent portion of the tube. An O-ring 177 is fitted in a groove, (not identified,) formed immediately inward of the open end of the neck 182. The rear end of discharge tube 32 is further formed so as to have an upwardly extending flange 186. Flange 186 extends from a portion of the base having the relatively large outer diameter, as opposed to the reduced diameter neck 182, and extends upwards towards suction tube 48. The flange 186 is shaped so as to have a first tapered surface 188 that extends from the portion of the tube adjacent neck 182. The opposed sur-

face of the flange extends at a right angle away from the discharge tube so as to form a 90° step **190**.

The rear end of the suction tube **48** is formed to have a neck **192** with a reduced outer diameter. More particularly, it can be seen that the neck **192** is narrowest at its open end, the end seated in drain tube **50**, and widest around the portion that is closest to the rest of suction tube **48**. In the depicted version of the invention, a pronounced circular step **194** separates neck **192** from the rest of the suction tube **48** though that may not always be the case. It should be understood that while the outer diameter of neck **192** is less than the outer diameter of the main portion of discharge tube **48**, the inside wall of the tube, including neck **192**, is of constant diameter. An annular rib **196** extends around the outer surface of suction tube **48** immediately rearward of the front end of the tube. The purpose of rib **196** will be explained hereinafter.

Splash shield **181**, now described by reference to FIGS. **10** and **10A**, is formed of flexible material such as polyvinyl chloride. The splash shield **181** is formed so as to have a base section **200** of generally oval shape. Base section **200** is formed to define two bores **202** and **204**. Bore **202** serves as the discharge bore and is the bore in which the front end of the discharge tube **32** is seated. To facilitate the securement of the splash shield to the discharge tube/suction tube subassembly, base section **200** is formed to have an annular lip **206** that extends inside bore **202**. When the splash shield **181** is fitted over discharge tube **32**, lip **206** in the annular groove **180** between the discharge tube **32** and nozzle **179**.

Bore 204 serves as the suction bore and is the bore in which the front end of suction tube 48 is seated. Bore 204 is dimensioned so that when the splash shield 181 is seated over the discharge tube 48, annular rib 196 abuts the inner wall of base section 200 that defines bore 204 to form a seal around the end of the bore 204.

The base section 200 is further formed to define a slit 183 that extends between bores 202 and 204 and opens towards the rear of the splash shield 181. When the splash shield is seated on the discharge tube-suction tube sub-assembly, the most forward web 178 seats in slit 183. In some versions of The invention, the web 178 may fully seat in slit 183.

Extending forward from base section 200, splash shield 181 is shaped to have an open-ended discharge head 208. Discharge head 208 defines a generally conically shaped discharge chamber 210. Discharge bore 202 opens into the center of discharge chamber 210, at the apex of the chamber. Suction bore 204 extends forward of the open end of discharge bore 202, curves towards the longitudinal axis of bore 202 and chamber 210 and opens into the side of discharge chamber 210. In preferred versions of the invention, suction bore 204 is in fluid communication with the chamber 210 through an opening 212 located immediately rearward of the edge of the wall defining the open end of chamber 210.

Splash shield 181 is further shaped to have an outwardly directed lip 214 around the open end of discharge chamber 210. Lip 214 is shaped so that forward surface thereof, the surface that is pressured against tissue has small channels 215. Channels 215

extend from the outer perimeter of lip 214 to the discharge chamber 210.

FIGS. 8 and 11 illustrate how the tip assembly 30 is locked to the handpiece 22. As can be seen in these Figures, tip assembly 30 is positioned towards the front end of the handpiece 22 so that the neck 182 of the discharge tube 32 is inserted through opening 154 of tip lock 152 and into the discharge head 150 of pump 24. The tip assembly 30 is pushed towards the handpiece 22 until flange 186 of the discharge tube 32 passes through opening 154. As the discharge tube passes through opening 154, tapered surface 188 of flange 186 abuts the complementary beveled surface 155 around opening 154. Further insertion of the discharge tube 32, thus serves to displace the tip lock 152 upwardly. Once flange 186 passes beyond tip lock 152, spring plate 160 forces the tip lock to return to its initial position. Thus, as depicted in FIG. 11, the inner surface of face plate 153 of tip lock 152 seats against step 190 of flange 186 to prevent unintended removal of the tip assembly 30. When the tip assembly 30 is so positioned, O-ring 177 forms a seal between discharge tube 32 and the surrounding inside wall of discharge head 150 of pump 24.

The coupling of the tip assembly 30 to handpiece 22 also results in the coupling of suction tube 48 into drain tube 50. More particularly, as the discharge tube 32 is being locked in position, neck 192 of the suction tube 48 is simultaneously seating in the open front end of drain tube 50. Owing to the outwardly directed taper of neck 192, the neck forms its own compression seal against the inside wall of drain tube 50.

It should be understood that, in some preferred versions of the irrigator **20** of this invention, handpiece **22** and tip assembly **30** are designed so that the distance between the front surface of the handpiece and the trailing edge of the closest web **178** is between 0.015 and 0.075 inches. In still more preferred versions of the invention, this distance is approximately 0.030.

Tip assembly **30** is uncoupled from the handpiece **22** by the simple upward depression of base plate **156** of tip lock **152**. This action causes the tip lock **152** to move upwardly relative to the handpiece as illustrated in FIG. **12**. This displacement of the tip lock **152** serves to space the portion of face plate **153** that defines the upper portion of opening **154** away from tip assembly flange **186**. Once this separation occurs, the tip assembly **30** is simply pulled away from the handpiece **22**.

Once the tip assembly **32** is coupled to handpiece **22**, the irrigator **20** is ready for use. The person using the irrigator only needs one hand to both grasp irrigator **20** and to depress trigger **44** that controls the on/off state of the irrigator and the rate at which it discharges fluid. Should continual high-speed operation of the irrigator be required, all one needs to do is depress trigger lock **118** to hold the trigger in the correct position. Irrigator **20** is then unlocked from high-speed operation by simple depression of trigger **44**.

When suction system **46** is actuated, the suction it draws causes a suction head to develop at opening **212** in the splash shield **181**. Since opening **212** is located relatively close to the open end of discharge chamber **210**, water and debris are immediately drawn into suc-

tion bore **204** upon their movement away from the surface against which the splash shield **181** is placed. This minimizes the extent to which material swirls or otherwise moves through the discharge chamber **210**. An advantage of the immediate removal of this material is that it eliminates the extent to which matter in the discharge chamber **210** obstructs the application of pulses of fluid to the surface to which the irrigator **20** is applied.

In versions of the invention wherein the splash shield **181** is provided with channels **215**, the channels serve as conduits through which air is drawn into the discharge chamber **210**. The venting of air into the discharge chamber around the perimeter of the splash shield-body site interface prevents the tissue still part of the patient from being unintentionally separated from the site to which the irrigator **20** is applied.

Still another advantage of the irrigator **20** of this invention is that splash shield **181** is snap fitted to the rest of the tip assembly **30**. This makes it possible to provide different shields that can be used with a single discharge tube-suction tube subassembly. Consequently, a medical facility does not have to maintain an inventory of different tip assemblies, the only difference between the individual assemblies being their splash shields.

The fluid and other material drawn through the suction tube **48** flows into the suction system **46** through drain tube **50**. Since neck **192** of suction tube **48** seats in drain tube **50**, there is essentially no leakage of the fluid and material as it flows into the drain tube. This is even the case when, owing to side load-

ing, the axis of suction tube 48 angles out of alignment with the axis of the handpiece 22.

Moreover, the diameter of the bore through drain tube 50 is greater than the diameter of the bore through suction tube 48. For example, in some versions of the invention, the diameter of the inside wall of suction tube 48 is approximately 0.200 inches and the diameter of the inside wall of the drain tube 50 is 0.250 inches. Thus, the interface between the two tubes 48 and 50 is not a constriction that could potentially serve as a clog point for material passing through the tubes. Moreover, owing to the positioning of drain tube 50 along the upper outer surface of the handpiece 22, the degree of curvature of the tube is kept to a minimum. In many preferred versions of the invention, the handpiece is formed so that drain tube 50 subtends an arc of greater than 90° and, more preferably, approximately 140° and the inner radius of the tube is greater than 0.75 inches and, in still more preferred versions of the invention, between 0.85 and 0.90 inches. Also, since there is not a "third" tube, connecting the portion of the drain tube 50 internal to the handpiece 22 with its downstream extension, the need to provide an additional fluid connection port to the handpiece is eliminated. The elimination of this fluid connection port, in addition to its cost savings, eliminates another connection point at which the material in the drain tube 50 could potentially clog the tube. Thus, the irrigator 20 of this invention is further designed to minimize the extent to which the material drawn through drain tube 50 will clog the tube.

Still another feature of this invention is that since spines 172 do not abut, drain tube 50 is visible along the top of the handpiece 22. The drain tube 50 itself is

formed out of transparent material. Thus the person using the irrigator need only look clown at the handpiece to view the material being drawn away from the site at which the irrigator is applied. This visual exposure of the drain tube **50** further makes it possible for medical personnel to monitor fluid and, material flow through the portion of the drain tube disposed in the handpiece **22**.

An alternative irrigator **220** of this invention is now initially described with respect to FIG. **13**. Irrigator **220** includes a handpiece **22***a* that is physically similar in structure and function to above described handpiece **22**. Tip assembly **30** is attached to the front of handpiece **22***a* to provide the tubes that serve as conduits through which fluid is discharged from the handpiece and a suction head is presented at the site to which the irrigator is applied. Irrigating fluid is supplied to handpiece **22***a* from bag **26** through supply tube **28***a*. A spike **221** located at the end of the supply tube **28***a* makes the fluid connection between the bag **26** and the tube. Power for energizing the handpiece **22***a* comes from a power pack **222** that is positioned outside the sterile field in which the handpiece **22***a* and tip assembly **30** are employed. The current from power pack **222** is applied to the handpiece **22***a* through a power cable **224**. Power conductors **60***a* and **62***a* and ground conductor **654***a* (FIG. **16**) are disposed within power cable **224**. A plug **226** at the end of power cable **224** plugs into a complementary socket **228** in the power pack **222**. In many preferred versions of the invention, the portions of the supply tube **28***a* and power cable **224** that extend from handpiece **22***a* are adhesively secured together. Often power cable **224** is longer than supply tube **28***a* to allow the power pack **222** to be placed at a more distal location to the sterile

field at which the irrigator **220** is being used than bag **26**. The adhesive employed to secure the supply tube **28***a* and power cable **224** is selected to allow these conduits to be readily separated to the extent needed to facilitate the placement of the power pack **222** outside of the sterile field.

The power pack **222**, as seen in FIGS. **14** and **15**, includes a housing **230** formed out of two shells **232** and **234** and a base plate **246**. Shells **232** and **234** are formed to provide the housing **230** with an indicator face **236** that extends diagonally away from the bottom surface of the power pack **222**. A handle **238** with a finger hole **240** extends downwardly below the portion of the housing **230** that defines indicator face **236**. Finger hole **240** performs two functions. First, it provides an opening for a person to grasp the power pack **222** so that it can be easily handled. Secondly, finger hole **240** serves as a opening which allows the power pack **222** to be mounted to a horizontally extending arm **242** of an IV pole **244** in a surgical suite (FIG. **13**).

A base plate **246** is secured between shells **232** and **234** and forms the bottom surface of the power pack **222**. A DC power plug **248** is mounted to base plate **246** to provide a connection between a charger, (not illustrated) and the power pack **222**. When the power pack **222** is charged, base plate **246** is positioned against a complementary surface of the charger from which a charger plug, complementary to plug **2483**, extends.

Power pack **222** is further shaped so that socket **228** to which power cable plug **226** is connected is also fitted to base plate **246**. This arrangement ensures that, when the power pack **222** is plugged into the

charger, it cannot simultaneously be used to energize the handpiece 22*a*. This prevents current from being directly supplied from the charger, which may not have the voltage protectors required for real-time patient connection, to the handpiece 22*a*.

Internal to the power pack 222 is a cluster of rechargeable cells 252. In the depicted version of the invention, power pack 222 is provided with seven series connected NiCad cells 252. Each cell 252, when fully charged can develop a potential of 1.2 Volts. A foam pad separates cells 252 from shell 234. A circuit board 254 is mounted below the portion of the housing 230 that defines indicator face 236. Circuit board 254 carries the components forming the circuitry that regulates the charging and discharging of cells 252. FIG. 15 further illustrates the label 256 positioned over indicator face 236 and the label 258 positioned over the side of the housing 230.

In preferred versions of the invention, power pack 222 is designed to have a center of gravity that is below and aligned with the center of finger hole 240. This construction facilitates the balancing of the power pack 222 when it is suspended from arm 242 of the IV pole 244.

FIG. 16 is a block diagram of the circuitry internal to power pack 222 that controls the charging and discharging of cells 252. The DC power plug 248, represented as opposed terminals, is connected to a cell charger 264. The cell charger 264 charges the cells 252 at one of two rates as a function of the potential across the cells.

Power pack 222 is configured to provide a pulse width modulated DC signal to handpiece 22*a*. The pulse is nominally one of two widths and is a function of the setting of the spring 66 internal to handpiece 22*a*. More particularly, when spring 66 is connected to conductor 60*a*, pulses having a relatively long "on" period are applied to the handpiece 22*a*; these pulses function as a high speed drive signal to the handpiece. When spring 66 is connected to conductor 62*a*, pulses having a relatively short "on" period are applied to handpiece 22*a*; these pulses function as a low speed drive signal to the handpiece. The potential of the low speed drive signal applied to motor 34 is further reduced to the extent spring 66 is in series with resistor 68.

The potential across the cells 252 is applied to handpiece 22*a* through either power conductor 60a or 62a and ground conductor 64*a*, all internal to power cable 224. The positive terminal of the cluster of cells 252 is connected to either power conductor 60*a* or power conductor 62*a* through a slow speed driver 266. Ground conductor 64*a* is selectively tied to the ground internal to the power pack 222 through a FET 268. The on/off period of FET 268 controls the width of the DC pulses applied to the handpiece 22*a*.

The on/off state of FET 268 is set by a speed regulator 270. The output signal produced by speed regulator 270 is itself a function of signals received from an oscillator 272; and a slow speed detector 274. Speed regulator 270 further monitors the potential across the cells 252 to adjust pulse width as a function of cell potential.

Oscillator 272 produces a constant frequency output signal. The output signal produced by oscillator 272 is, however, forced to ground if a power down circuit 276 determines that the voltage across the cluster of cells 252 has fallen below a set potential. The slow speed detect circuit 274 produces a slow speed signal based on the detection of one of either two signals states. First, slow speed detector 274 produces a slow speed signal when the slow speed driver 266 produces a signal indicating current is being supplied to the handpiece 22*a* through low speed power conductor 62*a*. Secondly, slow speed detector 274 produces the slow speed signal when it determines that the potential across the cluster of cells 252 has fallen below a set potential.

FIGS. 17A and 17B, when assembled together, form a schematic drawing of the electrical components internal to the power pack 222. Cell charger 264 includes a voltage suppressor 282 that is tied across the opposed terminal of the DC power plug 248. Whenever the potential across the DC power plug 248 exceeds a preset voltage, voltage suppressor 282 establishes a closed circuit across the power plug 248 to prevent excessive voltages from being applied to the other components internal to the power pack 222. A full-wave bridge rectifier 284 is also tied across the terminals of the DC power plug 248. Rectifier 284 performs two functions. First, it allows an AC signal to be applied to the power pack 222 for recharging the cells 252. Secondly, in the event the polarities of the DC signal applied to power plug 248 are reversed, it ensures that the positive signal is still applied to the other components of the cell charger 248. A filter capacitor 286 is tied between the output terminal of rectifier 284 and ground to minimize voltage variations in

the signal, the rail voltage, distributed downline from the rectifier. In the illustrated version of the invention, the rail voltage is further filtered by a capacitor **287** also tied between the rectifier **284** and ground. In preferred versions of the invention, an 18 to 35 VDC signal or a 15 to 25 VAC signal is applied to cell charger **264** in order to charge cells **252**.

The rail voltage from rectifier **284** is applied to the V+ terminal of a charging chip **288** designed regulate the charging of cells **252**. One particular charging chip **288** that can be employed as part of this invention is the MAX713 manufactured by Maxim. The signal from rectifier **284** is applied to charging chip **288** through a resistor **290** and a forward biased LED **292**. The emission of light by LED **292** serves as an indication that a charging current is being applied to the power pack **222**. Not shown are the program pin Connections and voltage divider associated with charging chip **288** that are used to set the various signal transitions of the charging chip described hereinafter.

The actual current employed to charge cells **252** comes from rectifier **284** through a buck converter consisting of FET **294**, inductor **296** and diode **298**. The FET **294** and inductor **296** are series connected together and are connected to the cells **252** through a forward biased diode **302**. Diode **298** is a reverse biased catch diode that is connected between the junction of FET **294** and inductor **296** and ground. The signal that turns FET **294** on and off is based on a DRIVE (DRV) signal generated by charging chip **288**. The DRIVE signal is applied to a resistor **304** and from the resistor to the emitter of transistor **306**. The collector of transistor **306** receives the rail voltage from rectifier **284** through a resistor **308**. The base of

transistor 306 is tied to the cathode of diode 292 to receive the V+ signal. Collectively, resistors 304 and 308 and transistor 306 level shift the rail voltage to a set voltage below rail voltage. In some versions of the invention, this difference is approximately 10 VDC. The actual times at when the level-shifted voltage is present at the collector of transistor 306, is a function of the assertion of the DRIVE signal.

The signal present at the collector of transistor 306 is applied to the bases of two series-connected transistors 310 and 312 that act as current drivers. The collector of transistor 310 is tied to rectifier 284 to receive the rail voltage. The emitter of transistor 310 is tied to the emitter of transistor 312. The collector of transistor 312 is tied to ground. The current-boosted signal present at the junction of emitter-emitter junction of transistors 310 and 312 is applied to the gate of FET 294 through a resistor 314.

Charging chip 288 asserts the DRIVE signal to cause the cells 252 to be charged at either a slow, "trickle," rate or a fast rate. The rate at which the charging chip 288 allows the cells to be charged is a function of the potential across the cells, current flow through the cells and the period of time cell charger 264, operates in at the fast rate. Charging chip 288 has BAT+ and BAT+ terminals that are connected directly across the cells 252 through which the chip monitors the potential across the cells. A capacitor 307 is also tied across the cells 252. The negative terminal of the cells 252 is connected to ground through a resistor 316. Charging chip 288 has a ground terminal that is connected to ground at the point resistor 316 is connected to ground. Charging chip 288 thus measures current flow through cells 252 as a function

of the voltage between its BAT+ and ground terminals. The charging chip basis its charging of the cells **252** in part on this current flow measurement.

The charging chip **288** also asserts a FAST-CHARGE (FCHG) signal whenever it is charging the cells **252** at the trickle rate. The FAST-CHARGE signal is applied to the emitter of a transistor **320** through a resistor **322**. The collector of transistor **320** receives the rail voltage from rectifier **284** through a forward biased LED **324**. The base of transistor **320** is tied to the cathode of LED **292**.

When cells **252** integral with power pack **222** are initially charged, cell charging chip **288** trickle charges the cells. This is accomplished by cycling the DRIVE signal so that it is on a relatively small fraction of time. When the DRIVE signal is on, FET **294** is turned on to allow inductor **296** to charge. During this part of the charging cycle current flows to the cells **252** so as to charge the cells. During trickle rate charging, the DRIVE signal is cycled at a rate so that when FET **294** is turned off, inductor **296** fully discharges through diode **298**. Consequently, during subsequent cycles when FET **294** is on, less current flows through inductor **296** to the cells **252**. In one version of the invention, the current supplied to the cells during trickle rate charging is 0.062 Amps.

During trickle rate charging, the FAST-CHARGE signal is asserted high by charging chip **288**. Consequently there is no current flow through transistor **320** and LED **324**. The LED **324** thus does not emit light.

Charging chip 288 monitors the potential across the cells 252 to determine if it reaches a level at which the cells can accept a higher current charge without being damaged. In one particular version of the invention, for the cells 252 to be fast charged, they must each have a potential of 0.4 Volts. Once charging chip 288 determines this potential, 2.8 Volts for the seven cells, has been reached, the on cycle time for asserting the DRIVE signal is increased; the cell charger 264 enters the fast charge mode.

The increase in the on cycle time for the DRIVE signal causes a like increase in the total percent of time in each cycle FET 294 is turned on. Specifically, charging chip 288 asserts the DRIVE signal for sufficient periods of time so that FET 294 is turned on for sufficient periods of time to ensure that inductor 296 does not fully discharge. Thus, during the periods of time FET 294 is turned on, there is substantially higher current flow to the cells 252 than when the cell charger 264 is operated in the trickle mode. In one particular version of the invention, when cell charger 264 is operated in the fast charge mode, current flow to the cells 252 is approximately 0.5 Amps.

When the cell charger 264 is in the fast charge mode, charging chip 288 negates the FAST-CHARGE signal low. The negation of the FAST-CHARGE signal turns on transistor 320 which, in turn, causes current to flow through LED 324. The current flow through LED 324 serves to cause the LED to emit a light indicating that the power pack 222 is being fast charged.

Cell charger 264 stays in the fast charge mode until one of three events occur. One event is the sensing

by the charging chip 288 of a drop in the voltage across cells 252. This voltage drop is interpreted by the charging chip 288 that the cells 252 are fully charged a an evidenced by the drop in current out of the cells. Secondly, charging chip 264 monitors the cells 252 for the voltage across the cells. In some versions of the invention, if this voltage reaches 14 Volts, the cell charger 264 ceases fast mode charging of the cells 252. Thirdly, charging chip 288 monitors the time the cell charger 264 is in the fast charge mode. If the time significantly exceeds the total time expected to fully charge the cells 252, fast mode charging is terminated In one version of the invention, the time for fully charging the cells is approximately 180 minutes; in these versions of the invention charging chip 288 is programmed to terminate fast mode charging after approximately 264 minutes. Once fast mode charging is terminated, charging chip 288 continues to assert the DRIVE signal necessary to trickle mode charge the cells 252. The continual trickle mode charging of the cells 252 prevents the cells from losing their charge.

The charging/discharging circuit internal to power pack 222 also includes a voltage regulator 328. Voltage regulator 328 is connected to the positive terminal of the cluster of cells 252. The voltage regulator produces a constant level +5 VDC signal that is used as a reference voltage and an operating voltage by the other components internal to the power pack 222.

The slow speed driver 266 is connected to the positive terminal of the cluster of cells 252. Conductor 60*a*, the conductor over which the high speed drive signal is supplied to the handpiece 22*a*, is connected directly to the cells 252 through the slow speed driver

266. Conductor 62*a*, the conductor over which the low speed drive signal is supplied to the handpiece 22*a*, is connected to cells 252 through a forward biased diode 330. A resistor 332 is connected across the extension of conductor 60a internal to slow speed driver 266 and the cathode of diode 330.

Slow speed driver 266 also includes a transistor 334. The emitter of transistor 334 is tied to the anode of diode 330. The base of transistor 334 is tied to the cathode of diode 330 through a resistor 336. The collector of transistor 334 is tied to the slow speed detector 274 to provide a signal whenever current flow to the handpiece is through conductor 62*a*.

The slow speed detector 274 includes a comparator 338 that provides a specific signal to indicate if the low voltage drive signal is to be outputted by power pack 222. The signal present at the collector of transistor 334 is applied to the noninverting input of comparator 338 through a resistor 339. In the illustrated version of the invention, the signal from transistor 334 is offset by the signal present at the junction of two series-connected resistors 340 and 342 which are connected between the +5 VDC source and ground. It will further be noted that a capacitor 343 is tied across resistor 342. Capacitor 343 filters out transient noise in the signal present at the junction of resistors 339, 340 and 342. Other capacitors are likewise tied to certain of the other resistors tied to ground. Since the position and purpose of these capacitors are understandable, they will not be further illustrated or described to minimize the complexity of this description and the accompanying drawings.

The voltage across the cluster of cells **252** is applied to the inverting input of comparator **338**. More particularly, the voltage across the cells **252** is applied to comparator **338** through a resistor **344**. A resistor **346** is tied between the inverting input of comparator **338** and ground. A feedback resistor **348** is tied between the output of comparator **338** and the noninverting input to provide hysteresis damping of the transitions of the output signal from the comparator.

Oscillator **272** includes a comparator **352**. The oscillator **272** also includes a voltage divider consisting of series-connected resistors **354** and **356** that are connected between the +5 VDC source and ground. The voltage present at the junction of resistors **354** and **356** is applied to the noninverting input to the comparator **352**. The inverting input of comparator **352** is tied to ground through a capacitor **358**. A resistor **360** provides a feedback loop between the output of comparator **352** and its noninverting input. A resistor **362** provides a feedback look between the output of comparator **352** and is inverting input. Oscillator **272**, when energized, produces a triangle-wave output signal having a frequency between 1.0 K Hz and 2.0 K Hz and, more particularly, approximately 1.3 K Hz.

Power down circuit **276** employs a comparator **364** to monitor the voltage across cells **252**. The cell voltage is applied to the noninverting input of comparator **364** through a resistor **366**. A resistor **368** is tied between the noninverting input of the comparator **364** and ground to provide the appropriate level adjustment to the signal applied to the comparator. The signal from rectifier **284** is also applied to the noninverting input of comparator **364** through a forward biased diode **370** and a resistor **372**.

A reference voltage is applied to the inverting input of comparator 364. This voltage is the voltage present at the junction of series-connected resistors 374 and 376 which are connected between the +5 VDC source and ground.

A feedback resistor 378 is connected between the output of comparator 364 and its noninverting input. A diode 380 is connected between output of comparator 364 and the junction of oscillator comparator 352 and capacitor 358. Diode 380 is reverse biased relative to comparator 364.

Speed regulator 270 provides the signal that turns FET 268 on and off. The on/off signal to FET 268 is produced by a comparator 384. The input to the noninverting input of comparator 384 is the signal present at the junction of comparator 352, capacitor 358 and diode 380. One input to the inverting input of comparator 384 is the output signal from comparator 338 of the slow speed detector 274. The signal from comparator 338 is applied to comparator 384 through a resistor 386. A second input to comparator 384 is the voltage across the cells 252 which is applied to the comparator 384 through a resistor 388. The signal from resistor 388 is a compensation signal which compensates for the changes in the signal from the slow speed detector 274 as function of voltage changes across the cells 252.

The signal applied to the inverting in-put of comparator 384 is level adjusted by the signal present at the junction of series connected resistors 390 and 392. Resistors 390 and 392 form a voltage divider between the +5 VDC source and ground. A resistor 394 can be placed in parallel across resistor 392 by the closing of

a switch **396** tied between resistor **394** and ground. Resistor **394** and switch **396** allows the signal presented to comparator **384** to be adjusted to allow further control of the on-period of the pulse width modulated signal produced by the power pack **222**.

The output signal of comparator **384** is applied to the gate of FET **268** through a resistor **398**. A diode **400** is reverse biased between the conductors internal to power pack **222** that are connected to power conductor **60***a* and ground conductor **64***a*. A capacitor **402** is connected between the anode of diode **400** and ground.

When handpiece **22***a* is operated at high speed, current flows from cells **252** directly through the slow speed driver **266** to conductor **60***a*. Consequently there is no current flow through diode **330**. As a result, transistor **334** is turned off and the slow speed driver forwards a zero-voltage signal to the slow speed detector **274**. As long as the potential across the cells **252** remains above a select potential, the signal present at the inverting input of the comparator **338** of slow speed detector **274** will be greater than the signal present at the noninverting input. Comparator **338** thus outputs a zero-voltage signal to comparator **384** of the speed regulator **270**.

The output signal from oscillator **272** is the signal applied to the noninverting input of comparator **384**. During the periods when the oscillator output signal is above the signal present at the inverting input, comparator **384** generates a +5 VDC signal that turns on FET **268**. As discussed above, during fast operation of the handpiece **22***a*, speed regulator **270** presents a zero-voltage signal to the noninverting input

of comparator 384. Thus, when the irrigator 220 is in this state, comparator 384 asserts a switch signal to turn FET 268 on for relatively long periods of time. For example, in one version of the invention, FET 268 has an on duty cycle of approximately 85% of each period of the output signal generated by the oscillator 272. This ensures that a relatively high average voltage is presented to the motor 34 as the high speed drive signal.

When the irrigator 220 is operated at slow speed, current flow to the handpiece 22*a* from cells 252 through diode 330 and conductor 62*a*. The current flow through diode 330 turns transistor 334 on. The turning on of transistor 334 presents a positive voltage to the noninverting input of comparator 338 of slow speed detector 274. The voltage from transistor 334, when combined with the voltage across resistor 342, is greater than the voltage present at the inverting input of comparator 338. Thus comparator 338 will assert a slow speed signal, a +5 VDC signal, to the inverting input of comparator 384.

The rise in the voltage presented to the inverting input of comparator 384 reduces the percent of time the voltage at that inverting input is greater than the output signal of oscillator 272 presented to the noninverting input. Thus, the percent of time comparator 384 asserts the drive signal to turn on FET 268 is reduced. In some preferred versions of the invention, the on duty cycle of FET 268, falls to approximately 70% of the period of the output signal from the oscillator 272. The increased off time of FET 268 causes power pack 222 to present a relatively low voltage signal, the low speed drive signal, to the handpiece 22*a*. The potential of the drive signal actually pre-

sented to the motor **34** will, of course, be function of the position of spring **66** relative to resistor **68**.

It should also be understood that speed regulator **270** also adjusts the on duty cycle of FET **268** as a function of the voltage across cells **252**. As the voltage across the cells **252** drops owing to their discharge, the signal presented to the inverting input of comparator **384** through compensation resistor **388** drops. The drop in the level of this signal serves to cause the duty cycle with which the comparator asserts a positive-voltage signal to increase. Thus, as the potential across the cells **252** drops, the on duty cycle of FET **268** increases to ensure that a drive signal with a substantially constant voltage is presented to the handpiece **22***a* as long as the potential across the cells stays above a given minimum level.

Slow speed detector **274** also asserts the slow speed signal to speed regulator **270** whenever the voltage across the cells **252** drops below a select potential. More particularly, as result of the voltage drop across the cells **252**, the signal presented to the inverting input of comparator **338**, will drop. If the signal at this inverting input falls sufficiently, it will be below the signal present at the noninverting input. If this drop in relative signal strength occurs, comparator **338** will assert the slow speed signal even though the irrigator is set for fast speed operation. Should this occur, the low speed drive signal will be presented to the handpiece **22***a* through conductor **60***a*. In one preferred version of the invention, the components forming the slow speed detector **274** are selected to cause the detector to assert the slow speed command signal when the potential across the cells falls below 7.4 VDC.

The power down circuit 276 inhibits operation of the power pack 222 when the potential across the cells 252 drops to a level below which further discharge might cause damage to the cells. More particularly, as long as the voltage across the cells 252 remains above a select level, the signal present at the noninverting input of comparator 364 will be above the voltage of the signal present at the inverting input. Comparator 364 will thus output a signal that will prevent forward biased current flow through diode 380. In some preferred versions of the invention, comparator will assert an output signal as long as the voltage across the cells 252 remains above approximately 6.0 VDC.

If, however, the voltage across cells 252 falls below the set value, the signal present at the noninverting input of comparator 364 will be less than the signal present at the inverting input. The output of comparator 364 will go to ground. Consequently, current will flow through diode 380 and a ground signal will thus be presented to the noninverting input of comparator 384 of speed regulator 270. Since the signal present at the inverting input of comparator 384 is a positive-voltage signal, the output of comparator 384 will likewise be at ground and hold FET 268 in the off state. The turning off of FET 268 prevents current flow from the power pack 222 to the handpiece 22*a*.

When the power pack 222 is placed back in its charger, the signal from rectifier 284 is applied to the noninverting input of comparator 364 through diode 370 and resistor 372. The signal from the rectifier 284 will be of sufficient potential to overcome the positive feedback that is supplied to the noninverting input through resistor 378. Thus, the signal from the recti-

fier 284 causes comparator 364 to again assert a positive-voltage signal.

Irrigator 220 has the same basic advantages as previously described irrigator 22. Irrigator 220 further includes a power pack 222 that can be used to energize the handpiece 22*a*. In some situations it may be more economical to provide this power pack 222 than a use-once battery pack.

Moreover, owing to the separation of power cable 224 from supply tube 28*a*, power pack 222 may be held outside of the sterile field in which the other comporents of the irrigator 220 are used. Thus, the power pack 222 need not be subjected to the sterilization practices used to sterilize medical instruments placed in the sterile field. This further serves to reduce the costs of supplying an energization current to the handpiece 22*a* of irrigator 220 of this invention.

The power pack 222 itself is especially designed to facilitate its repetitive use. The circuitry internal to the power pack 222 ensures that, even when the handpieces 22*a* with which it is used are operated at low speed, the cells 252 are evenly discharged. Consequently, the individual cells 252 do not develop separate internal electro-chemical "memories" regarding the magnitude of the charges they store. This ensures that when the power pack 222 is recharged, all the cells 252 will recharge to the greatest extent possible. The full recharging of the cells 252 ensures the power pack 222 will, even after numerous rechargings, be able to deliver the potential required to operate the handpiece 22*a* at high speed.

Also, the power pack **222** is configured so that when the charge falls, the width of the drive signal increases. Thus, the potential of the drive signal applied to the handpiece remains constant even though the voltage across the cells may be dropping. Since this potential does not vary for, a given trigger setting the discharge of fluid from the handpiece **22***a* remains constant for a given trigger setting even as the potential across the cells **252** falls. The person using the irrigator **220** of this invention thus is not required to engage in real time adjustment of the trigger setting as a result of the discharge of the cells.

Moreover, once the potential across the cells **252** falls below a first level, slow speed detector **274** causes the power pack to produce low voltage drive signals to the handpiece **22***a*. This accomplishes two tasks. First. it conserves the charge stored in the power pack **222** to increase the period of time with which it can be used. Secondly, by preventing fast speed operation of the irrigator **220**, it provides an indication to medical personnel that the power pack **222** will soon be discharged to the point where it can no longer supply an energization voltage to the handpiece **22***a*.

The power down circuit **276**, as discussed above, prevents operation of the power pack when such operation could potentially cause damage to cells **252**. Moreover, often after NiCad cells are discharged, the potential across the cells increases. Power down circuit **276** prevents reactivation of the power pack **222** when the cells **252** are in this state. Thus, power down circuit **276**, inhibits the use the power pack **222** even though the real-time potential across the cells **252** provides an impression that they are storing enough

charge to energize a handpiece 22*a* for a significant period of time.

FIGS. 18 and 19 illustrate an alternative nozzle assembly 410 that can be fitted to the front end of discharge tube 32 of the tip assembly 30 of this invention. Nozzle assembly 410 includes a cylindrical base 412 that is secured over the open end of discharge tube 32. Base 412 has a front face 414 that is formed with a number of openings 416 through which the irrigating fluid is discharged. A post 418 extends forward from the center of face 414.

A rotating spray head 420 is secured to post 418. The spray head has a body formed out of a number of spaced apart shoulder sections 422. In preferred versions of the invention, the number of shoulder sections 422 equals the number of openings 416 formed in the base 412 of the nozzle assembly 410. The shoulder sections 422 are formed to have bottom surfaces 423 that extend diagonally outwardly from the center of the spray head 420. A nose 424 extends forward from the center of base where the shoulder sections 422 meet. In the illustrated version of the invention, nose 424 is formed with a slight outwardly projecting taper to facilitate the manual grasping and rotation of the spray head 420. The surface of the nose 424, however, does not subtend the spaces between the shoulder sections 422 through which the fluid stream flows.

Spray head 420 is formed with an axially extending bore 426 to facilitate the fitting of the spray head over post 418. The post 418 is formed with its own locking head 428, that is larger in diameter than the post itself, to hold the spray head 420 to the base 412. Nose 424 of the spray head 420 is formed with a counter-

bore **430** in which the locking head **428** of the post is seated. Typically, the spray head **420** is snap secured over post **418**. While not illustrated, in some preferred version of the invention, locking head **428** and the portion of nose **424** that defines counterbore **430** are formed with interlocking teeth for holding the spray head in a specific position on the post **418**.

A tip assembly **30** in which nozzle assembly **410** is installed is used like a standard tip assembly. When the medical personnel want a direct discharge of irrigating fluid onto a body site, spray head **420** is set on post **418** so that the interstitial spaces between the shoulder sections **422** are aligned with openings **416**. When spray head **420** is so positioned, the irrigation fluid will be directly discharged onto the body site at which the tip assembly **30** is directed.

When diffused spray is desired, spray head **420** is reset so that shoulder sections **422** are aligned with openings **416**. The fluid discharged through the openings thus strikes the base surfaces **423** of the shoulder sections and is diverted radially outwardly toward the surface of the splash shield **181** that define discharge chamber **210** (FIG. **10A**.) The fluid is reflected off the splash shield **181** and flows towards the body site.

Tip assembly **30** with nozzle assembly **410** provides either a direct or diffused spray of irrigating fluid. This allows real time adjustment of the spray pattern without requiring medical personnel to change tip assemblies. Still another advantage of this version of tip assembly **30** is that since the tip assembly can be used to deliver irrigating fluid in two spray patterns, the need to keep two separate tip assemblies, that only differ by nozzle design, is eliminated.

Also, nozzle assembly **410** of this invention diffuses the discharged irrigation fluid after the fluid has already been discharged from the discharge tube **32**. It does not impose a restriction on fluid flow while the irrigating fluid is in the discharge tube **32**. Thus, nozzle assembly **410** of this invention, when employed to diffuse fluid flow, does not impose a pressure drop on the fluid as it is discharged which can adversely effect the efficiency of the pump **24**

The foregoing description has been directed to several preferred embodiments of the invention. It should be clear that the structure of the invention may differ from what has been described. For example, there is no requirement that all versions of the invention employ the described tip lock;. Other versions of the invention may employ other tip locks and even other tip assemblies. Also, there is no requirement that handpiece **22** be manufactured out of two opposed shells. In some versions of the invention, the handpiece may consist of a single piece housing that is formed with a channel in which the drain tube **50** is fitted. In these, as well as other versions of the invention, it may be desirable to employ other means to secure the drain tube in the housing. For example, it may be desirable to employ an adhesive to bond the drain tube to a wall internal to the housing that forms the channel in which the drain tube is seated.

It should likewise be understood that not all versions of the handpiece of this invention may include pumps and complementary motors for providing the discharge force for the fluid pulses. In some versions of the invention, the fluid may actually be pumped from a pump that is separate from the handpiece. In these versions of the invention, supply tube **28** or

some conduit connected to supply tube 28 may be connected directly to the discharge head of the handpiece.

Furthermore, in versions of the invention in which the on/off and speed control is employed, the trigger structure may be different from what has been described. In some versions of the invention, the trigger may be a press-button that is normally biased to hold the complementary wiper in the off state. Alternatively, the trigger may be a component that is integrally formed with the body handpiece. In these versions of the invention, the trigger may be a cantilever arm that is integrally molded as part of the body of the handpiece. This arm would be connected to the wiper so that movement of the arm would result in displacement of the wiper. In these versions of the invention, owing to the molding of the cantilever arm, when the arm is its normal, static state it would hold the wiper in off position. The application of manual force to deflect the arm would move the wiper to position in which the wiper would electrically connect the motor to the batteries or power pack.

Also, the tip assembly may be structurally different from what has been described. For instance, in some version of the invention, discharge tube 32 may be provided with an outwardly extending ring that forms a seal with the splash shield 181 and suction tube 48 is formed with an annular groove in which a complementary seal integral with the splash shield seats. It should further be recognized that some tip assemblies may not even have suction tubes. Alternative nozzles may also be provided. For example, the nozzle may be integrally formed with the discharge tube. Also, while the necks of the discharge tube and

suction tube are shown as being separated from the bodies of these tube by distinct steps, that need not always be the case.

Moreover, in some versions of the invention, it may be desirable to mount a slidable splash shield to the tip assembly. Typically, but not always, these tip assemblies do will not include a suction tube. In these versions of the invention, the splash shield will move along the length of the discharge tube. An O-ring may be mounted in the portion of the splash shield seated around the discharge tube to prevent back leakage of irrigating fluid.

Also, it may be desirable to provide some sort of locking mechanism to hold the splash shield to the rest of the tip assembly. For example, the opposed surfaces of the splash shield **181** that form slit **183** can be provided with a complementary boss-in-bore that form a snap lock. Also, the channels **215** may not be required. In the place of the channels, small bores may be formed in the portion of the spray shield **181** that define discharge chamber **210**. Furthermore different constructions of the adjustable nozzle are possible. In some nozzles constructed according to this invention, it may be possible to set the rotating spray head to an intermediate position in which it deflects only a fraction of the fluid stream discharged out of the fixed base of the nozzle.

Also, while one particular trigger assembly for regulating the potential of the drive signal applied to the motor **34** has been disclosed, it should be clear that others may be employed. Thus, in some versions of the invention, resistor **68** may be eliminated. In these versions of the invention, the number of differ-

ent speeds at which the irrigator would operate would be a function of the number of separate power conductors tied from the battery pack or rechargeable power pack to the handpiece. If, for example, there were three power conductors, than the irrigator would only operate at three speeds. In the power pack employed with these versions of the invention, the necessary modifications would have to be made to its internal regulator to determine through which of the three conductors there was current flow. It would similarly be necessary to design the speed regulator to ensure that it could cause three different PWM drive signals to be produced.

Alternative constructions of the trigger assembly are also possible. The loop in the spring **66** may not always be necessary to define a pivot point for the spring. Still in other versions of the invention, other members may be employed as the wiper that provides contact at various positions along resistor **68** and with contact **70**. In most versions of the invention, it is contemplated that the wiper be formed of material that, in addition to being conductive, is also flexible.

Also, some trigger locks may be designed to hold the trigger in intermediate positions in addition to the position required for high speed operation.

It should similarly be recognized that the power pack may employ alternative circuitry for charging cells **252**. For example, it may desirable to build an alternative power pack with a plug that allows it to be coupled to a conventional 120 VAC wall outlet. In these versions of the invention, the power pack may then incorporate a step-down transformer to lower the AC signal to a level at which it can be rectified.

Likewise, alternative circuitry for ensuring that the cells **252** are uniformly discharged and/or are not excessively discharged may be employed. For example, in some versions of the invention it may be desirable to provide a number of different voltage regulators to the power conductors for providing drive signals of different potentials. Alternatively, the power conductors may be connected to a switchable voltage regulator. In this version of the invention, the voltage produced by the regulator would be based on the determination of which power conductor was serving as the conduit over which the drive signal was being applied to the handpiece **22***a*. Alternatively, zener diodes may be used to set the voltage of the drive signal applied to the handpiece **22***a* from the power pack **222**.

Therefore, it is the object of the appended claims to cover all such modifications and variations as come within the true spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A medical irrigator comprising:

a handpiece, said handpiece having: a body having a front end; a discharge head in the body that is directed toward the front end of the body through which fluid is discharged;

and a drain tube mounted in said body so as to have an open end adjacent the front end of said body; and

a tip assembly for connection to said handpiece, said tip assembly including: a discharge tube having a first neck that is seated in said discharge head; and a suction tube that is attached to said DRAIN tube, said suction tube having a second neck that is seated in said open end of said drain tube.

2. The irrigator of claim 1, wherein said drain tube is a single-piece tube having a first section mounted in said body of said handpiece and a second section that extends beyond said handpiece for connection to an external suction unit.

3. The irrigator of claim 1, further including a pump disposed in said handpiece wherein said pump forces fluid through said discharge head and said discharge tube.

4. An irrigating handpiece for use with a discharge tube, said irrigating handpiece comprising:

a body shaped to have a handgrip and a front end spaced from said handgrip, said front end formed with an opening for receiving the discharge tube;

an open-ended discharge head in said body from which irrigation fluid is discharged, said discharge head being located adjacent the front end of said body and being dimensioned to receive the discharge tube; and

a tip lock seated in said front end of said front end of said body, said tip lock having: a face plate located forward of said discharge head, said face

plate being positioned so that the discharge tube extends across said face plate; and a flexible biasing member extending between said face plate and said body for holding said face plate in a static position relative to said discharge tube so that when said face plate is so positioned, said face plate engages a complementary surface of the discharge tube.

5. The irrigation handpiece of claim 4, wherein said face plate and said biasing member of said tip lock are integrally formed as a single unit.

6. The irrigation handpiece of claim 5, wherein said biasing member is a spring arm.

7. The irrigation handpiece of claim 4, further including a drain tube seated in said body that extends from said front end for receiving a suction tube.

8. The irrigating handpiece of claim 4, further including a pump disposed in said body wherein said discharge head is part of said pump and said pump forces irrigation fluid through said discharge head.

9. An irrigating handpiece for receiving a tip assembly having a discharge tube and a suction tube, said irrigating handpiece comprising:

a body shaped to have a handgrip, a front end spaced from said handgrip, and a channel that extends from said front end towards said handgrip;

a discharge head fitted in said body, said discharge head having an opening to which the discharge

tube is coupled and through which fluid is discharged into the discharge tube; and

a single-piece drain tube, said drain tube having a fist section that is disposed in said channel and that has an open end adjacent said front end of said body for receiving the suction tube and second section integral with said first section that extends out from said body.

10. The irrigating handpiece of claim 9, wherein: said channel is contained within an opening formed in an outer surface of said body so that said first section of said drain tube is at least partially visible from outside of said body; and said drain tube is formed from transparent tubing.

11. The irrigating handpiece of claim 9, wherein said body is formed from two shell sections and said first section of said drain tube is disposed between said shell sections.

12. The irrigating handpiece of claim 9, wherein said channel extends at least partially through said handgrip of said body.

13. The irrigating handpiece of claim 9, further including a tip lock movably secured to said front end of said body for removably securing the tip assembly to said handpiece.

14. A tip assembly for use with an irrigating handpiece, said tip assembly including:

an elongated discharge tube having a circular outer surface with an outer diameter, a front end, and a rear end opposite said front end;

a first neck integrally formed with said rear end so as to extend rearwardly therefrom;

an annular seal disposed over an outer surface of said first neck; and

a tab integrally formed with said discharge tube that extends away from said outer surface of said discharge tube, said tab being located adjacent said rear end of said discharge tube.

15. The tip assembly of claim 14, further including a suction tube that is connected to said discharge tube by at least one web and that has a front end adjacent said front end of said discharge tube and a rear end adjacent said rear end of said discharge tube.

16. The tip assembly of claims 14, further including a spray shield that is removably secured over said first end of said discharge tube and said first end of said suction tube.

17. The tip assembly of claim 15, wherein said suction tube has an outer surface having a diameter, an inner wall having a diameter and a second neck that extends rearwardly from said rear end of said suction tube, said second neck having an outer surface with a diameter less than said diameter of said outer surface of said suction tube and an inner wall with a diameter equal to the diameter of the inner wall of said suction tube.

18. The irrigator of claim 1, further including a lock assembly integral with said handpiece for releasably holding said tip assembly to said handpiece.

19. The irrigator of claim 1, wherein said second neck has an outer surface and said drain tube and said suction tube are collectively dimensioned so that the outer surface of said second neck abuts an adjacent inner surface of said drain tube.

20. The irrigator of claim 19, wherein the outer surface of the second neck of said suction tube has a tapered profile such that outer surface has small diameter adjacent an open rear end of said suction tube and an increasing diameter distal from the open rear end.

21. The irrigator of claim 20, wherein said suction tube has a main portion located forward of said second neck and said suction tube is shaped to have et constant inner diameter from the open end of said suction tube, through said second neck and through at least a section of said main portion adjacent said second neck.

22. The irrigator of claim 1, further including a supply tube that is connected to said handpiece and that is in fluid communication with said discharge head through which the fluid is supplied to said discharge head.

23. A medical irrigator comprising:

a handpiece, said handpiece including: a body having a front end; a discharge head through which irrigation fluid flows, said discharge head having an opening adjacent the front end of the body through which the irrigation fluid is discharged; and a drain tube mounted in said body through which a suction is drawn, the drain tube

having an open front end located adjacent the opening of said discharge head; and

a tip assembly, said tip assembly having: a discharge tube with an open rear end, the rear end of said discharge tube being seated in the opening of said discharge head so that irrigation fluid flows directly from the discharge head into the discharge tube; and a suction tube, said suction tube having an open rear end with a circumferentially extending outer surface, the rear end of said suction tube being seated in the front end of said drain tube and, said drain tube and said suction tube being collectively dimensioned so that the outer surface of the rear end of said suction tube abuts an adjacent inner surface of the front end of said drain tube.

24. The irrigator of claim 23, further including a lock assembly integral with said handpiece for releasably holding said tip assembly to said handpiece.

25. The irrigator of claim 23, wherein said drain tube is a single-piece tube having a first section mounted in said handpiece body and a second section that extends out of said handpiece body for connection to an external suction unit.

26. The irrigator of claim 23, wherein said tip assembly suction tube is formed to have a main body and a neck, said neck forms the rear end of said suction tube, said main body and said neck each have an outer diameter and an inner diameter and wherein the outer diameter of said neck is less than the outer diameter of said main body and the inner diameter of

said neck and the inner diameter of a section of said main body adjacent said neck are identical.

27. The irrigator of claim 26, wherein the outer surface of the rear end of said suction tube has a tapered profile such that the outer diameter of the rear end of said suction tube increases distally from the opening in the rear end.

28. The irrigator of claim 23, wherein: said suction tube is formed so as to have a main portion contiguous with the rear end; the rear end and said main portion of said suction tube each have an inner diameter; and the rear end and an adjacent section of the main portion of said suction tube have a constant inner diameter.

29. The irrigator of claim 23, further including a supply tube that is connected to said handpiece and that in fluid communication with said discharge head through which the irrigation fluid is supplied to said discharge head.

30. The irrigator of claim 23, further including a pump disposed in said handpiece wherein, said pump forces the irrigation fluid through said discharge head and said discharge tube.

31. The irrigating handpiece of claim 4, wherein said face plate is formed with an opening through which the drain tube extends and an edge surface of said face plate that defines the opening selectively engages the complementary surface of the drain tube.

32. The irrigating handpiece of claim 31, wherein said face plate is formed so that the opening in said

face plate is circumferentially enclosed by said face plate.

33. The irrigator of claim 4, further including a supply tube that is connected to said handpiece and that is in fluid communication with said discharge head through which the irrigation fluid is supplied to said discharge head.

34. An irrigating handpiece for use with a discharge tube, said irrigating handpiece including:

a body, said body having a first end, the first end being formed with an opening in which the discharge tube is inserted;

a discharge head located in said body, said discharge head having an open end in said body adjacent the first end in which the discharge tube is received and through which irrigation fluid is discharged into the discharge tube; and

a tip lock mounted to said body, said tip lock including:

a lock plate having an engagement surface, said lock plate being movably mounted to the first end of said body so as to have a first position in which the engagement surface engages a complementary surface of the discharge tube to prevent release of the discharge tube and a second position in which the engagement surface is spaced from the discharge tube to allow release of the discharge tube;

a biasing member extending between said body and said lock plate for holding said lock plate in the fist position; and

a manually displaceable release button connected to said lock plate, said release button being connected to said lock plate so that displacement of said release button results in displacement of said lock plate from the first position to the second position.

35. The irrigating handpiece of claim 34, wherein said lock plate, said biasing member and said release button of said tip assembly are formed as a one-piece component.

36. The irrigating handpiece of claim 34, wherein said lock plate is shaped to define an opening through which the discharge tube is inserted and the engagement surface of said lock plate at least partially defines the opening.

37. The irrigating handpiece of claim 36, wherein said lock plate is formed so that the opening through which the discharge tube is inserted is circumferentially surrounded by said lock plate.

38. The irrigation handpiece of claim 34, wherein said lock plate is shaped so that a surface opposite the engagement surface has a beveled profile.

39. The irrigating handpiece of claim 34, wherein said release button is a plate that is integrally formed with said lock plate.

40. The irrigating handpiece of claim 34, further including a drain tube mounted in said body for receiving a suction tube.

41. The irrigating handpiece of claim 34, further including a supply tube that is connected to said handpiece and that is in fluid communication with said discharge head through which the irrigation fluid is supplied to said discharge head.

42. The irrigating handpiece of claim 34, further including a pump disposed in said handpiece wherein, said pump forces the irrigation fluid through said discharge head and said discharge tube.

43. The irrigating handpiece of claim 9, further including a supply tube that is connected to said body and that is in fluid communication with said discharge head through which the fluid is supplied to said discharge head.

44. The irrigating handpiece of claim 9, further including a pump disposed in said body wherein, said pump forces the fluid through said discharge head and said discharge tube.

45. An irrigating handpiece for receiving a tip assembly having a discharge tube and a suction tube, said irrigating handpiece including:

a body at least partially shaped to form a handgrip and a front end for receiving the discharge tube and the suction tube;

a lock assembly mounted to the front end of said body for releasably securing the discharge tube and the suction tube to said body;

a discharge head disposed in said body, said discharge head having an open end adjacent the front end of the body for receiving the discharge tube wherein, said discharge head receives irrigation fluid and discharges the irrigation fluid through the open end into the discharge tube; and

a single piece drain tube, said drain tube having a first end mounted in said body and a second end integral with the first end that extends outside of and away from said body, the first end of said drain tube being adjacent the front end of said body and being in fluid communication with the suction tube.

46. The irrigating handpiece of claim 45, wherein the first end of said single drain tube is positioned adjacent the front end of said body and has an opening for receiving the suction tube.

47. The irrigating handpiece of claim 45, wherein: said body is formed to define a channel; and the first end of said drain tube is fitted in the channel.

48. The irrigating handpiece of claim 45, wherein: said body is formed with an elongated opening; the first end of said drain tube is fitted in said body to be visible through the elongated opening; and said drain tube is formed from transparent tubing.

49. The irrigating handpiece of claim 48, wherein the elongated opening and said drain tube extend at least partially through the handgrip of said body.

50. The irrigating handpiece of claim 45, wherein said drain tube extends at least partially through the handgrip of said body.

51. The irrigating handpiece of claim 45, further including a supply tube that is connected to said handpiece and that is in fluid communication with said discharge head through which the irrigation fluid is supplied to said discharge head.

52. The irrigating handpiece of claim 45, further including a pump disposed in said handpiece wherein, said pump forces the irrigation fluid through said discharge head and said discharge tube.

53. The irrigating handpiece of claim 14, wherein said tab is formed to have a tapered surface that faces towards the rear end of the discharge tube that extends away from the outer surface of the discharge tube towards the front end of the discharge tube and a stepped surface that faces towards the front end of the discharge tube that extends perpendicularly away from the adjacent outer surface of the discharge tube.

54. A tip assembly for use with an irrigating handpiece, said tip assembly including:

an elongated discharge tube having a front end, and a rear end opposite said front end;

a first neck integrally formed with the rear end of said discharge tube so as to extend rearwardly therefrom;

an elongated suction tube secured to said discharge tube, said suction tube having a front end adjacent the front end of said discharge tube and a

rear end adjacent the rear end of said discharge tube, wherein the rear end of the suction tube has inner and outer diameters; and

a second neck integrally formed with the rear end of said suction tube so as to extend rearwardly therefrom, said second neck having a tapered profile so as to have an outer diameter that decreases rearwardly from the rear end of said suction tube and an open end wherein, said second neck has an inner diameter and the inner diameter of the rear end of said suction tube and of the inner diameter of said second neck are identical.

* * * * *

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

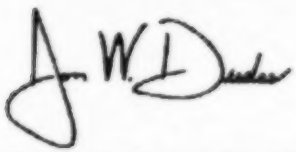
Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.



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NOTICE

If the application for this patent was filed on or after December 12, 1980, maintenance fees are due three years and six months, seven years and six months, and eleven years and six months after the date of this grant, or within a grace period of six months thereafter upon payment of a surcharge as provided by law. The amount, number of timing of the maintenance fees required may be changed by law or regulation. Unless payment of the applicable maintenance fee is received in the United States Patent and Trademark Office on or before the date the fee is due or within a grace period of six months thereafter, the patent will expire as of the end of such grace period.

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(12) **United States Patent**
Arnett et al.

(10) **Patent No.: US 7,144,383 B2**
(45) **Date of Patent: *Dec. 5, 2006**

(54) **SURGICAL/MEDICAL IRRIGATING HANDPIECE WITH VARIABLE SPEED PUMP, INTEGRATED SUCTION AND BATTERY PACK**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

920,270	A	1/1909	Chambers
832,686	A	4/1910	Schroeder
738,563	A	9/1903	Wiseman
798,353	A	9/1905	Pettingell
1,317,851	A	10/1919	Arnett
1,505,279	A	8/1924	Hixson
1,578,207	A	3/1926	Schaffer
1,846,396	A	2/1932	Hamilton

(Continued)

FOREIGN PATENT DOCUMENTS

DE 24 16 009 6/1975

(Continued)

OTHER PUBLICATIONS

Copy of Stiletto, Phaco/Abbey Lab and Instrument, photos (10 photos) Jan. 23, 1993.

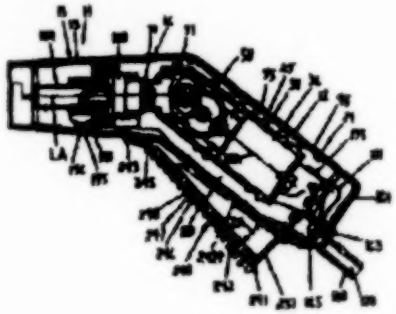
(Continued)

Primary Examiner—Denise Pothier

(57) **ABSTRACT**

A medical/surgical irrigating handpiece with both a discharge line through which fluid is applied to the site and a suction line through which the discharge fluid is drawn away. The handpiece has a variable speed pulse pump. A simple, variable-speed motor actuates the pump to regulate the pumping rate. Power to actuate the motor comes from a battery pack that connects to the handpiece. A control mechanism attached to the handpiece regulates the energization signal applied to the motor so as to regulate motor speed.

46 Claims, 17 Drawing Sheets



U.S. PATENT DOCUMENTS

3,812,886 A 5/1935 Lowry
2,112,829 A 3/1938 Lloyd
2,139,653 A 12/1938 Rutlidge
2,197,995 A 4/1940 Crowley
2,243,385 A 5/1941 Page
2,243,299 A 5/1941 Brown
2,494,888 A 1/1950 Daley
2,551,791 A 11/1950 Selsh
2,595,491 A 5/1952 Schweitzer
2,634,885 A 4/1953 Nash
2,662,495 A 12/1953 Riley
2,684,049 A 3/1954 Hollis
2,727,676 A 12/1955 Henderson
2,733,713 A 2/1956 Kalnick
2,781,154 A 2/1957 Meredith
2,882,496 A 8/1959 Thomas
2,847,007 A 8/1958 Poe
2,874,696 A 2/1959 Broad
2,988,771 A 10/1959 Hanna
2,993,854 A 7/1961 Hanna
3,001,208 A 9/1961 Freedman
3,014,624 A 12/1961 Hess et al
3,079,272 A 6/1963 Fitch
3,044,465 A 7/1962 Anderson et al.
3,048,171 A 8/1962 Sheesley
3,065,549 A 11/1962 Brun
3,070,880 A 12/1962 Tack
3,139,258 A 6/1964 Peters
3,208,145 A 9/1965 Turner
3,227,198 A 1/1966 Mastrogiy
3,237,304 A 3/1966 Brun
3,261,618 A 8/1966 Carpenter
3,295,371 A 1/1967 Smith
3,316,849 A 5/1967 Schumann
3,371,537 A 11/1967 Knox et al
3,379,039 A 12/1967 Johnson et al
3,393,673 A 7/1968 Mastrogiy
3,436,967 A 12/1968 VonDerhd et al.
3,473,410 A 2/1969 Claremch
3,474,343 A 2/1969 Chemen et al
3,448,784 A 6/1969 Schmitt
3,452,748 A 7/1969 Bradshaw
3,484,121 A 12/1969 Quinton
3,508,546 A 4/1970 Rogers et al
3,513,190 A 6/1970 Taylor
3,561,433 A 2/1971 Kovach
3,601,164 A 8/1971 Brun
3,605,596 A 9/1971 Robinson
3,615,687 A 1/1972 Gitto
3,653,377 A 6/1972 Rebold
3,702,141 A 11/1972 Weissbrun
3,703,170 A * 11/1972 Richman, Jr. 601/162
3,713,533 A 1/1973 Reimuth
3,731,611 A 5/1973 Barber et al.
3,731,676 A 5/1973 Rebold
3,749,090 A 7/1973 Stewart
3,762,411 A 10/1973 Lloyd et al.
3,765,882 A 10/1973 Lallemand et al.
3,768,472 A 10/1973 Rudnick et al.
3,771,522 A 11/1973 Wagnild et al
3,784,795 A 1/1974 Kessler et al.
3,794,831 A 2/1974 Illman
3,833,349 A 12/1974 Resnick
3,861,385 A 1/1975 Kovach
3,883,874 A 5/1975 Lambert
3,889,675 A 6/1975 Stewart
3,895,741 A 7/1975 Magnel
3,949,753 A 4/1976 Dunbleton
3,965,914 A 6/1976 Rosenberg
3,982,540 A 9/1976 Ross
3,996,266 A 10/1976 Vollweiler
3,983,874 A 11/1976 Newman
4,080,339 A 2/1977 Ross et al
4,038,495 A 6/1977 Wong
4,038,498 A 6/1977 Pamplikian
4,081,142 A 1/1977 Tuttle
4,099,527 A 7/1978 Howell
4,111,391 A 9/1978 Wallis
4,123,071 A 10/1978 Cheatham et al.
4,205,676 A 6/1980 Humphrey et al.
4,215,436 A 8/1980 Armstrong
4,216,889 A * 12/1980 Wright 433/86
4,248,589 A 2/1981 Lewis
4,250,872 A 2/1981 Tanori
4,257,416 A 3/1981 Poggie
4,267,847 A 5/1981 Wasserstrom
4,279,326 A 6/1981 Schori
4,278,823 A 6/1981 Phillips et al.
4,278,078 A 7/1981 Smith
4,282,867 A 8/1981 Du Toit
4,289,130 A 9/1981 Nehring
4,290,434 A 9/1981 Shuler
4,294,251 A 10/1981 Greenwald et al.
4,300,548 A 11/1981 Stanley
4,301,977 A * 11/1981 Carnahan et al. 239/331
4,313,689 A 2/1982 Steele
4,314,560 A 2/1982 Halligan et al.
4,340,889 A 8/1982 MacNeill
4,350,477 A 9/1982 Mizzi
4,395,208 A 7/1983 McCullough
4,434,810 A 3/1984 McCullough
4,434,805 A 3/1984 Hanson
4,438,343 A 3/1984 Bertsch et al.
4,438,348 A 3/1984 Peyman et al
4,438,406 A 3/1984 McCullough
4,441,849 A 5/1984 Willing
4,449,527 A 5/1984 Kaldewey
4,451,099 A 5/1984 Mabuo
4,460,350 A 7/1984 Somerville et al.
4,468,221 A 8/1984 Mayfield
4,472,130 A 9/1984 McCullough
4,482,345 A 11/1984 Chow et al.
4,484,399 A 11/1984 Lacey
4,489,250 A 12/1984 Nehring
4,498,894 A 1/1985 Wuchinich
4,502,502 A 3/1985 King
4,508,532 A 4/1985 Dawes et al.
4,508,507 A 4/1985 Vale
4,512,886 A 4/1985 McCullough
4,515,532 A 5/1985 Willing
4,519,385 A 5/1985 Atkinson et al.
4,520,973 A 7/1985 Lester et al.
4,524,770 A 6/1985 Akers et al.
4,535,773 A 8/1985 Yoon
4,537,602 A 8/1985 Lissi
4,537,899 A 8/1985 Sato
D281,535 S 11/1985 Atkinson et al.
4,552,130 A 11/1985 Kinoshita
4,553,957 A 11/1985 Williams et al.
4,561,434 A 12/1985 Atkinson
4,564,358 A 12/1985 Carlson
4,589,846 A 4/1986 Campbell et al.
4,583,531 A 4/1986 Matsuhira
4,592,349 A 6/1986 Ebling et al.
4,596,558 A 6/1986 Bodai et al.
4,604,748 A 7/1986 Mall
4,604,089 A 8/1986 Bassingthwaite et al.
4,621,770 A 11/1986 Sapse
4,634,420 A 1/1987 Spinosa et al.
4,636,621 A 1/1987 Atkinson
4,647,328 A 3/1987 Diamond
4,655,197 A 4/1987 Atkinson
4,655,906 A 4/1987 Thayer et al
4,655,752 A 4/1987 Honkanen et al.

4,695,754 A 9/1987 Stubenrauch
4,695,765 A 9/1987 Swift
4,698,829 A 5/1987 Nakang
4,697,653 A 9/1987 Ogle et al.
4,697,140 A 9/1987 Olsen
4,698,869 A 9/1987 Mashimoto
4,705,500 A 11/1987 Reimels et al.
4,741,678 A 5/1988 Nakang
4,748,978 A 6/1988 Nakajima
4,799,369 A 21988 Bazz et al.
4,704,105 A 9/1988 Reimels et al.
4,765,105 A 9/1988 Reimels et al.
4,765,508 A 0/1988 Akkerma
4,778,448 A 10/1988 Perkin et al.
4,799,481 A 1/1989 Timmon et al.
4,817,599 A 4/1989 Davey
4,837,868 A 2/1989 Lehn
4,872,837 A 10/1989 Issalene et al.
4,892,464 A 1/1990 McCullough et al.
4,911,821 A 3/1990 McCullough et al.
4,923,458 A 5/1990 Illami et al.
4,927,340 A 5/1990 McCullough
4,935,005 A 6/1990 Hasan
4,941,872 A 7/1990 Pelin et al.
4,957,483 A 9/1990 Chatar et al.
4,978,282 A 12/1990 Yo et al.
4,982,738 A 1/1991 Hanstorp et al.
5,019,070 A 5/1991 Lindm
5,037,431 A 8/1991 Summer et al.
5,048,488 A 9/1991 Grolle et al.
5,049,071 A 9/1991 Davis et al.
5,053,022 A 10/1991 Barlow
5,054,547 A 10/1991 Frank et al.
5,057,013 A 10/1991 Fleet
5,098,387 A 3/1992 Wiese et al.
5,098,426 A 3/1992 Peterson et al.
5,108,420 A 4/1992 Wu
5,128,508 A 4/1992 Sandeinger et al.
5,142,723 A 8/1992 Lustig
5,147,392 A 9/1992 Kollas et al.
5,178,779 A 12/1992 Glenberg
5,178,629 A 1/1993 Kollas et al.
5,180,714 A 1/1993 Sundstrom et al.
5,188,591 A 2/1993 Dorsey, III
5,195,956 A 3/1993 Phillips
5,195,959 A 3/1993 Smith
5,197,648 A 3/1993 Im
5,205,309 A 4/1993 Clawson et al.
5,224,929 A 7/1993 Bandyopadhyay
5,244,459 A 9/1993 Hill
5,261,905 A 11/1993 Dorsey, III
5,269,798 A 12/1993 Grolle et al.
5,281,214 A 1/1994 Wilkins et al.
5,295,976 A 3/1994 Bales et al.
5,303,733 A 4/1994 Casale et al.
5,308,351 A 4/1994 Weldon
5,322,502 A 6/1994 Dorse
5,372,586 A 6/1994 Kollas
5,333,603 A 8/1994 Schramm
5,334,140 A 8/1994 Phillips
5,336,208 A 8/1994 Hobson et al.
5,340,351 A 8/1994 Zimmer
5,388,277 A 2/1995 Phillips
5,388,642 A 2/1995 Casale et al.
5,391,148 A 2/1995 Dorsey
RE34,788 E 1/1995 Casale
5,431,876 A 7/1995 Dalrad et al.
5,447,496 A 9/1995 Dorsey, III
5,448,597 A 9/1995 Zimmer
5,470,305 A 11/1995 Arnett et al.
5,484,402 A 1/1996 Bassler et al.
5,487,649 A 1/1996 Dorsey, III et al.
5,514,089 A 5/1996 Vaillancourt et al.
5,532,796 A 6/1996 Dorsey, III
5,542,440 A 10/1996 McCabe et al.
5,573,504 A 11/1996 Dorsey, III
5,578,000 A 11/1996 Gayl et al.
5,586,977 A 12/1996 Dorsey, III
5,607,391 A 3/1997 Klinger et al.
5,609,575 A 3/1997 Jacobsen
D383,809 S 11/1997 Kollas et al.
5,707,351 A 1/1998 Dorsey, III
5,718,668 A 2/1998 Arnett et al.
5,746,721 A 5/1998 Frank et al.
5,792,096 A 8/1998 Pelis et al.
5,792,168 A 8/1998 Pelis et al.
5,807,313 A 9/1998 Dalk et al.
5,810,778 A 9/1998 Chin et al.
5,827,218 A 10/1998 Bigwan et al.
5,924,448 A 7/1999 Wan
5,941,891 A 8/1999 Valley et al.
6,022,309 A 2/2000 Arnett et al.
6,050,754 A 4/2000 Frank et al.
6,099,772 A 8/2000 Kinary et al.
6,099,984 A 8/2000 Hannigan et al.
6,108,494 A 8/2000 Jacobs et al.
6,136,894 A 12/2000 Tremaine et al.
6,142,744 A 11/2000 Shipp
6,178,847 B1 1/2001 Humphreys, Jr. et al.
6,179,887 B1 1/2001 Hennigan et al.
6,200,292 B1 3/2001 Frank et al.
6,213,978 B1 4/2001 Hobson et al.
6,302,527 B1 10/2001 Hennigan et al.
6,398,238 B1 2/2002 Tims et al.
6,371,984 B1 4/2002 Jackson et al.
6,394,996 B1 5/2002 Lamothe et al.
6,471,660 B1 10/2002 Hannigan et al.
6,485,452 B1 11/2002 Frank et al.
6,623,443 B1 9/2003 Hobson et al.
6,626,827 B1 9/2003 Pelis et al.
6,685,669 B1 2/2004 Dell et al.
2001/0025160 A1 9/2001 Pelis et al.
2002/0002357 A1 1/2002 Jackson et al.

FOREIGN PATENT DOCUMENTS

EP 0 258 901 3/1988
FR 1 325 670 3/1963
GB 1 264 138 2/1972
GB 2 067 474 A 6/1981
WO WO81/01794 7/1981
WO WO81/02315 8/1981
WO WO85/05982 9/1985
WO WO86/04247 8/1986
WO WO91/13638 9/1991
WO WO92/21388 12/1992
WO WO93/17733 9/1993
WO WO94/13199 6/1994
WO WO94/19050 9/1994
WO WO94/23773 10/1994

OTHER PUBLICATIONS

ELI DuCharme Hydrosurgery, Pump believed published before Apr. 19, 1993.

Medtronic—Unique Products for Advanced Operative Laparoscopy 798—3bd.

Select One...™ Minimal Access Surgery System, Introducing the SelectOne™ Bipolar Instrument, Combined Aspen Surgical Systems, Copyright Jul. 1993, 3Bd.

Select One...™ Minimal Access Surgery System, The Modular Instrument System for Surgical Endoscopy, SelectOne System by Combined, Aspen Surgical Systems believed published before Apr. 19, 1993.

Davol—Shuttle-Flo™ Irrigator, Davol, Inc.; Instruction booklet P 041082-0, 9/1/18, Nov. 1990.

Count On US (Introducing Over 900 Patented Unified Quality Components), Unidyn-Quali., 1993
Rain® Bird® Brochure Irrigator, Why do I need the Rain Sensor Irrigator? Rain® Bird®, for believed published before Apr. 19, 1993
"Simultaneous pulsatile lavage and/or irrigation with suction . . ."
Pulsatile Lavage Debridement System, Interface No. 82-898-5150-04-05/7.5M CHS Zimmer, Inc., Snyder Labs Inc. 1982.
Hydro-Dimmy™ /Hydro-Dimmitor™ Information Booklet Installation/Operating Instructions for "Quick-Disconnect" Probe Tips (2 sheets) believed published before Apr. 19, 1993
Rain®Irrigator Is No Longer An Issue, Hydro-Dimmitor System, 1993/JD PP/ICM Intl. 1992, Rain Bird® Corp. Tuebingen, West Germany
A Fully Integrated Laparoscopic Irrigation and Instrumentation System, Cabot Medical, Langhorne, PA Apr. 1993, HIM, L/T (4 sheets)
Advances in Pulsavage, The Irrigation Pump System, Cabot Medical, Langhorne, PA Apr. 1993 (1 sheets)
InvESET™ . Fluid Management System User' Manual, Smith & Nephew Dyonics Inc., copyright 1992, P/N 0201470.
Davol, Arthro-Pak® , Instructions For Use, 0500217-0 9810 C R Bard, Inc. Cranston RI, Jan. 1990
Davol, Arthro-Pic High-Flo Irrigator, Bard, OP-AP0015000 Aug. 1992 '04 C R Bard Inc. Cranston, RI.
'Al Fluid Control System, For Precise Control of all Arthroscopic Procedures, 70 2020 5450-0, 1992 3M
Davol, Instruments for Use, Hospital— ™ Reclosed/Irrigator, BARD, 034009-0 (2 sheets) Jan. 1993
"Introducing the multi-functional instrument for virtually every laparoscopic case", USSC, Auto Suture Company, Copyright 1992, 530322 pp. 1004 Jul. 1992
Davol's Answers to Plaintiff's First Set of Interrogatories dated Jun. 1996
Davol's Supplemental Answers to Plaintiff's First Set of Interrogatories dated Feb. 14, 1997
Deposition of Roger B. Dennis, pp. 1-177, with Index pp. 1-19 and corrections and signature pages 1-3, dated May 7, 1997
Rule 26(a) (2) Report Report of Dr. Hewith M. Hansen Relating to Davol's Defenses to Stryker's Infringement Claims Under the '402 Patent dated Oct. 29, 1997 including Exhibits A-D
Rule 26 (a) (2) Report Report of Roger B. Dennis Relating to Davol's Defenses to Stryker's Infringement Claims Under the '402 Patent dated Oct. 30, 1997 including exhibits A-D
Rule 26 (a) (2) Rebuttal Report Report of Dr. Hewith M. Hansen, M.D. Relating to Stryker's Infringement of United States Patent No. 5 391 145 and United States Patent No. 5 586 977, dated Dec. 8, 1997
Deposition of Hewith M. Hansen, pp.1-281 with index pages 1-32 dated Feb. 13, 1998.
Davol's Supplemental Answers to Plaintiff's First Set of Interrogatories dated Feb. 16, 1997
Ruling on Claim Construction Disputes dated Apr. 24, 1998.
Trial-vol. IV, IV, Nov. 17, 1998 (Hagen-Cross; Dennis-direct, voir dire, Cross) multi-chromal fiber-optic rotary multipage 35-41 (actual pp. 526-705).
Trial-vol. V, Nov. 18, 1998 (Dennis-direct) multipage 623-705, actual pp. 3-44
Memorandum Opinion and Order Denying Motion for Judgment as a Matter of Law dated May 26, 1999.
Author D. Little (Tudo) Dec. 8, 1992 letter to Davol.
Bard (Rod Cliby) Oct. 16, 1992 fax to John Shoemock.
Author D. Little (Tudo) Nov. 12, 1992 fax to John Shoemock (Davol).
Author D. Little (Tudo) Dec. 17, 1992 letter to John Shoemock.
Author D. Little (Tudo) Jan. 25, 1993 letter to John Shoemock.
Saline Pump Development Program, Davol Inc., Jan. 18, 1993, Cambridge, MA.
Talpeth Nov. 2, 1992 search for John Shoemock re Scroll Pumps.
Author D. Little (Davol) Sep. 8, 1992 letter to Albert Solis.
Davol (Dilvia) Jan. 4, 1993 letter to Author D. Little.
Saline Scroll Pump Development Program.
Scroll Technology in Medical Products.

* cited by examiner

U.S. Patent Dec. 5, 2006 Sheet 1 of 17 US 7,144,383 B2

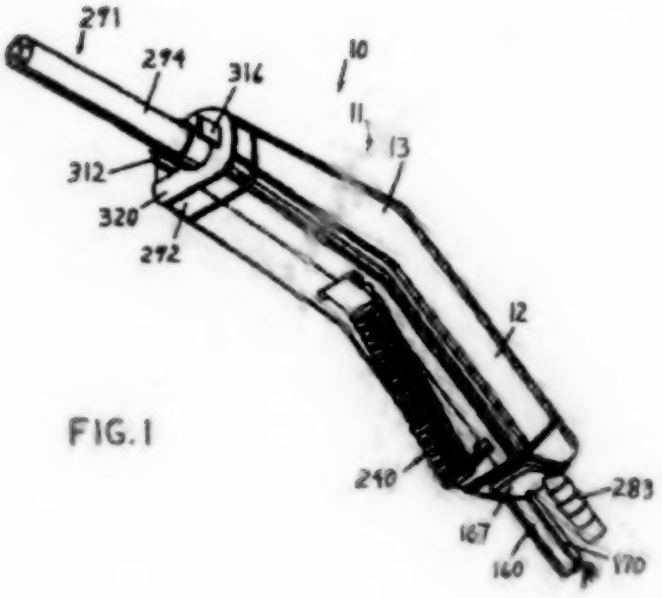


FIG. 1

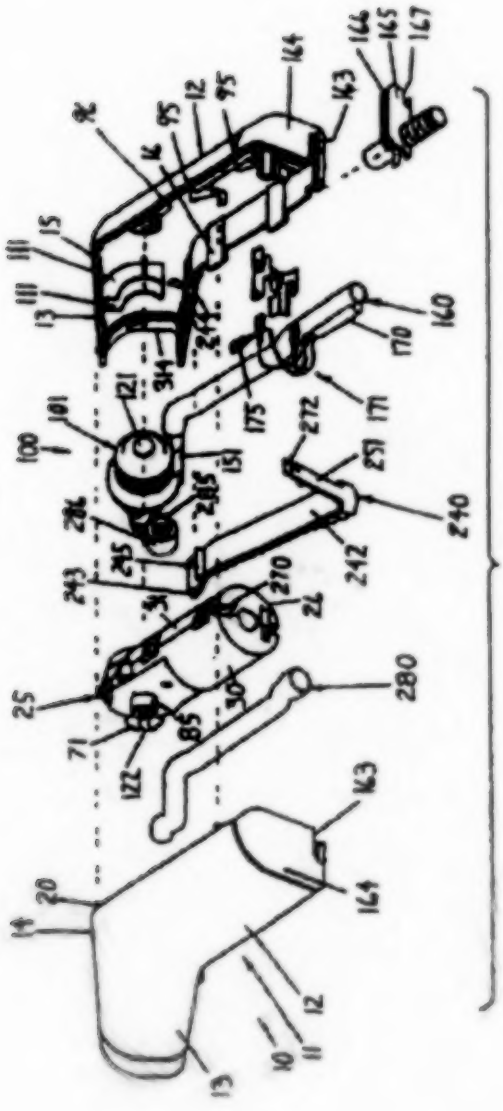

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FIG. 2

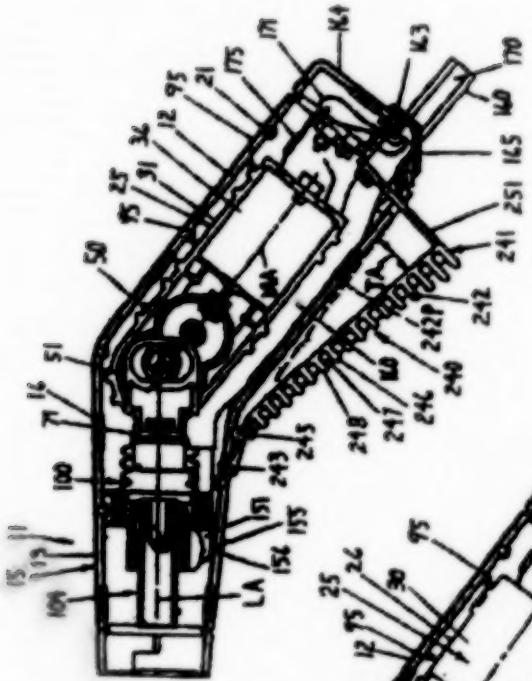


FIG. 4

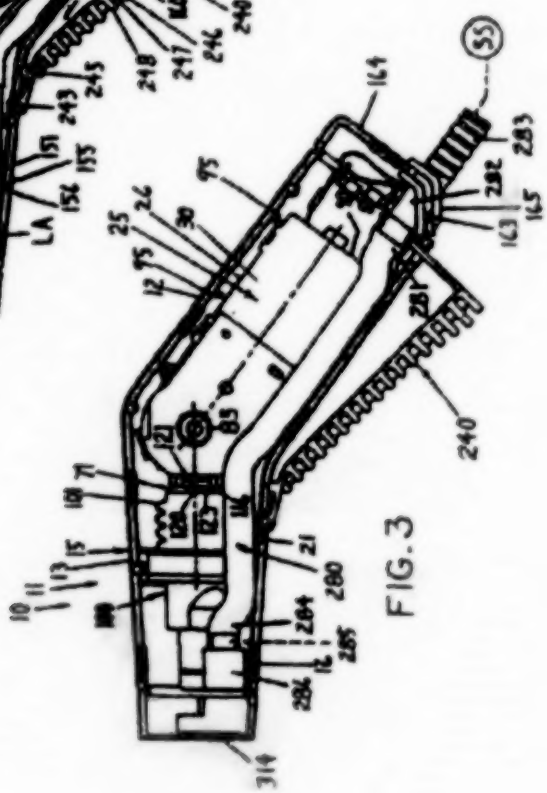


FIG. 3

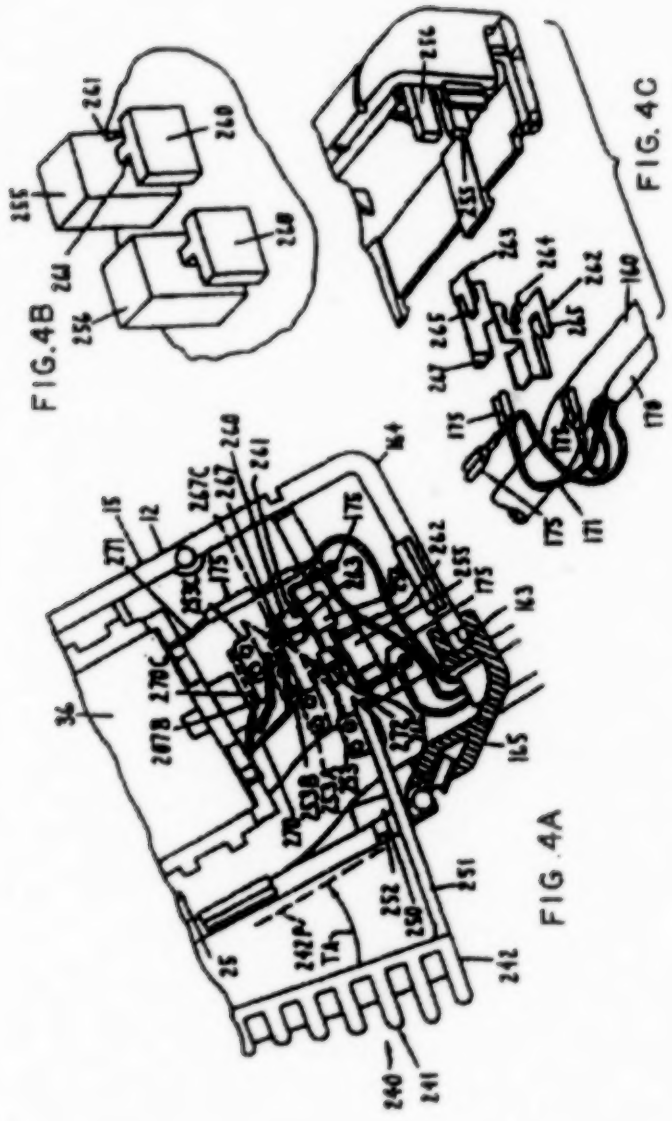
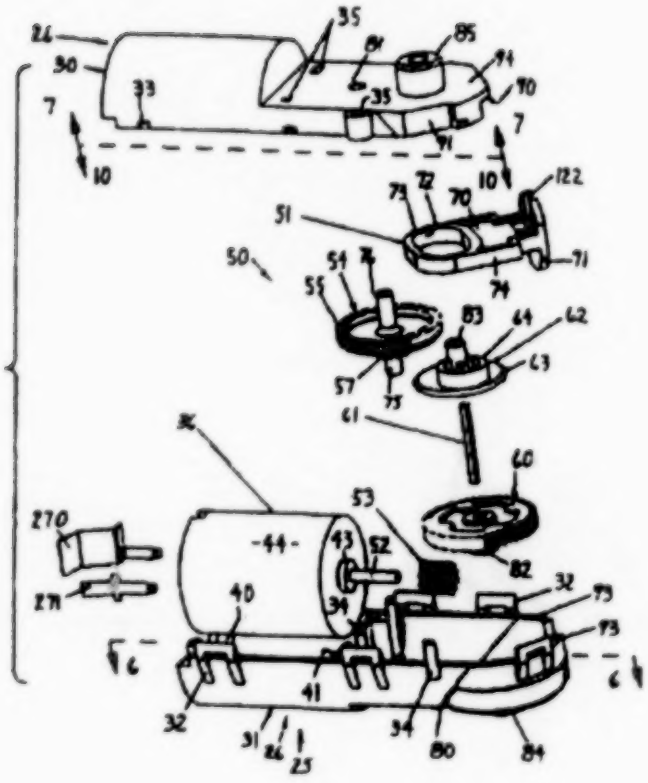


FIG. 4A

FIG. 4B

FIG. 4C

FIG. 5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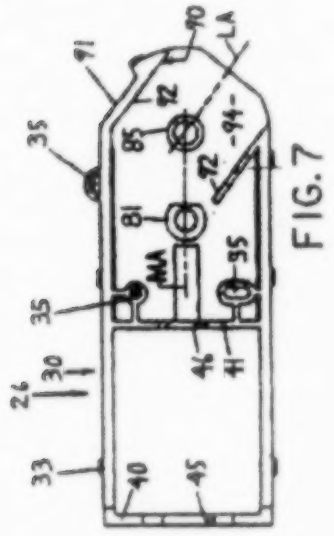

FIG. 7

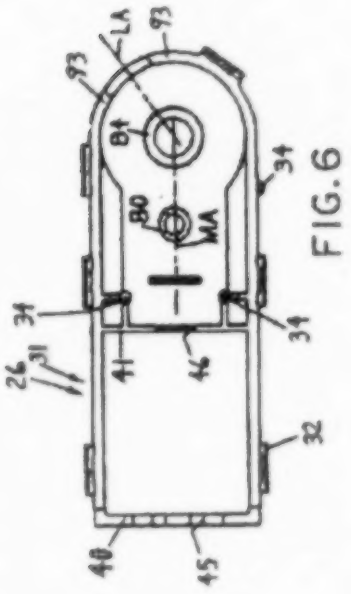

FIG. 6

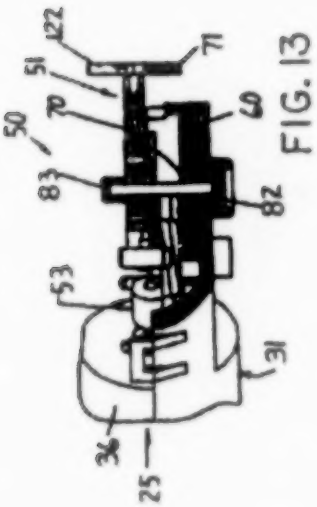

FIG. 13

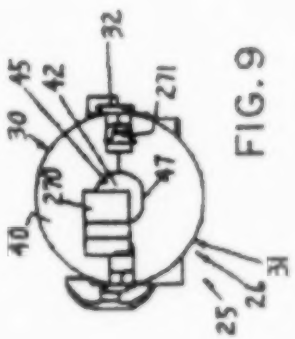

FIG. 9

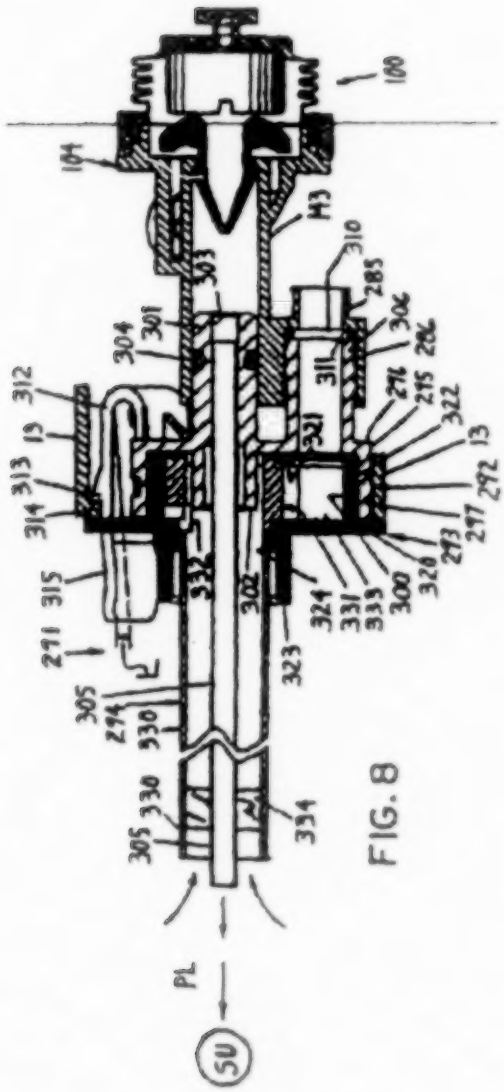
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FIG. 8

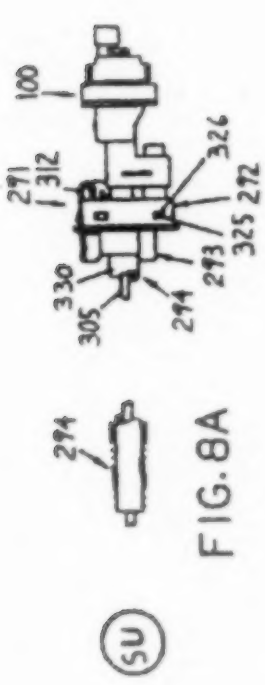
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FIG. 8A

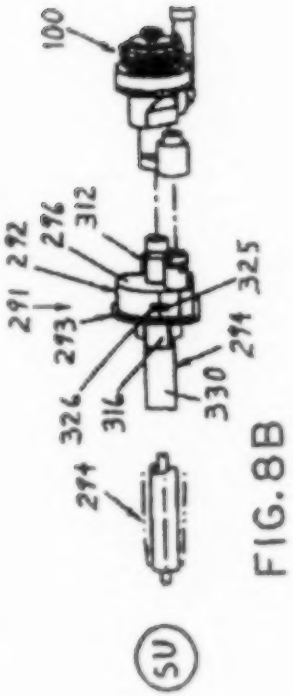
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FIG. 8B

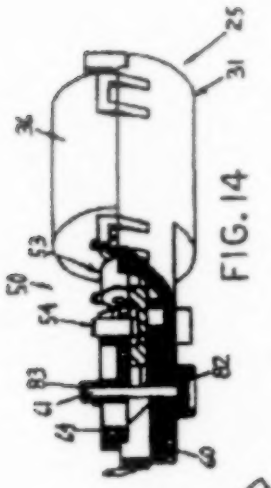


FIG. 14

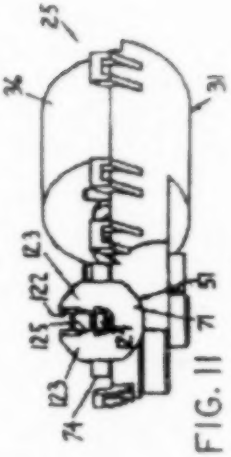
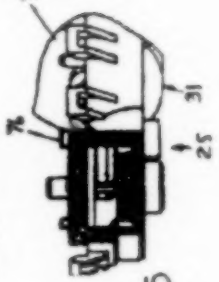


FIG. 11



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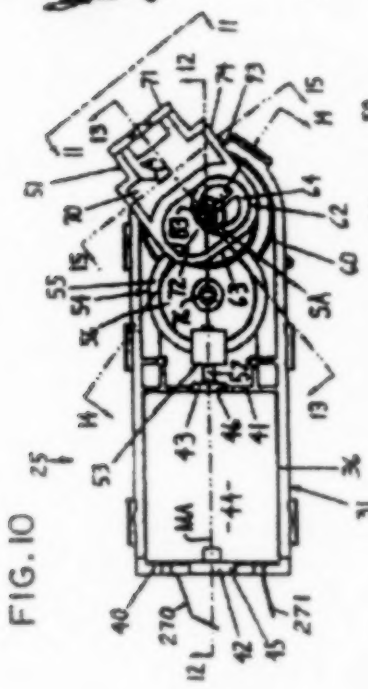

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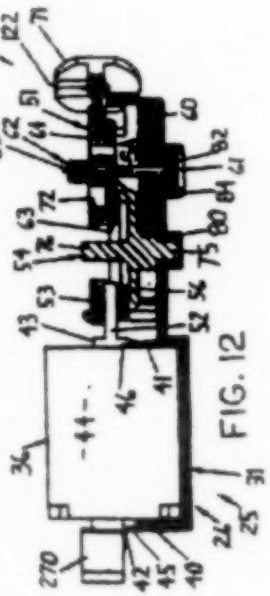

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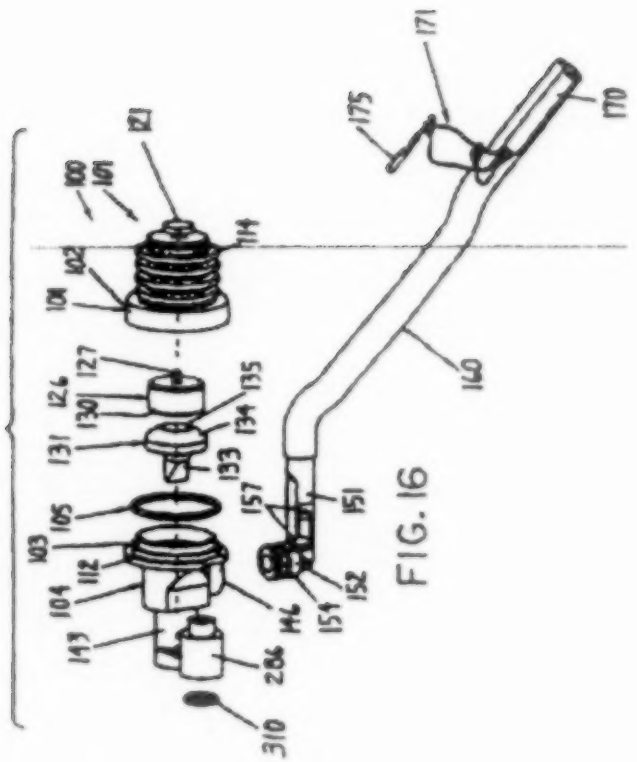
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FIG. 16

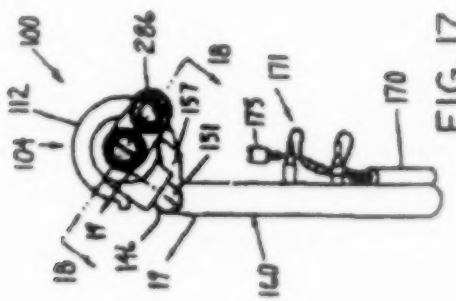
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FIG. 17

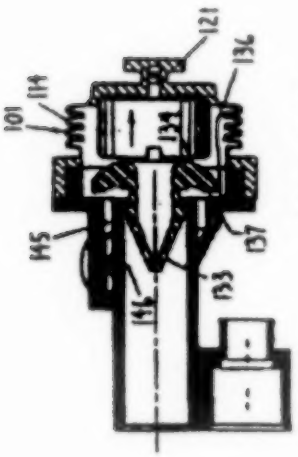
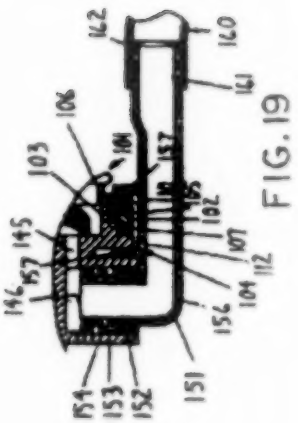


FIG. 18A



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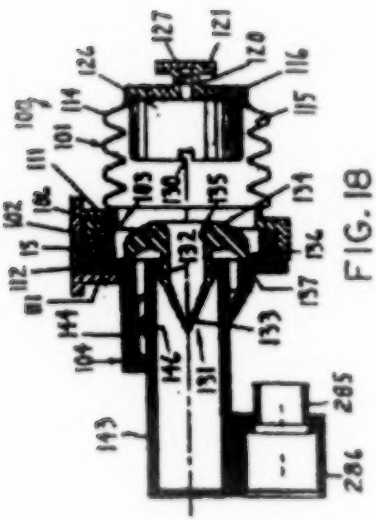

FIG. 18

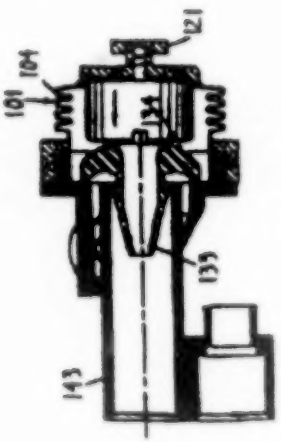

FIG. 18B

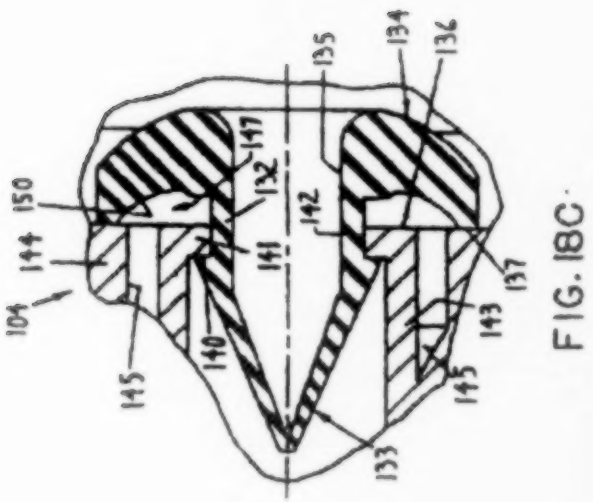

FIG. 18C

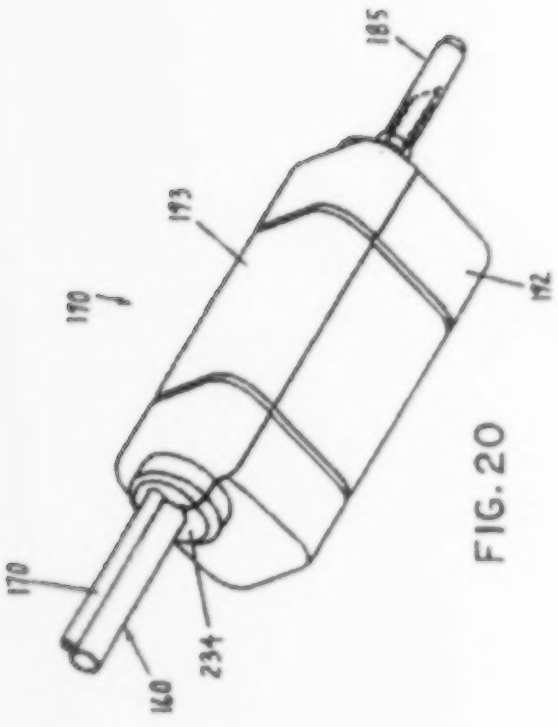

FIG. 20

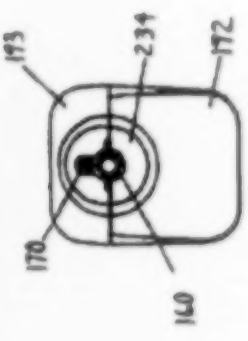

FIG. 21

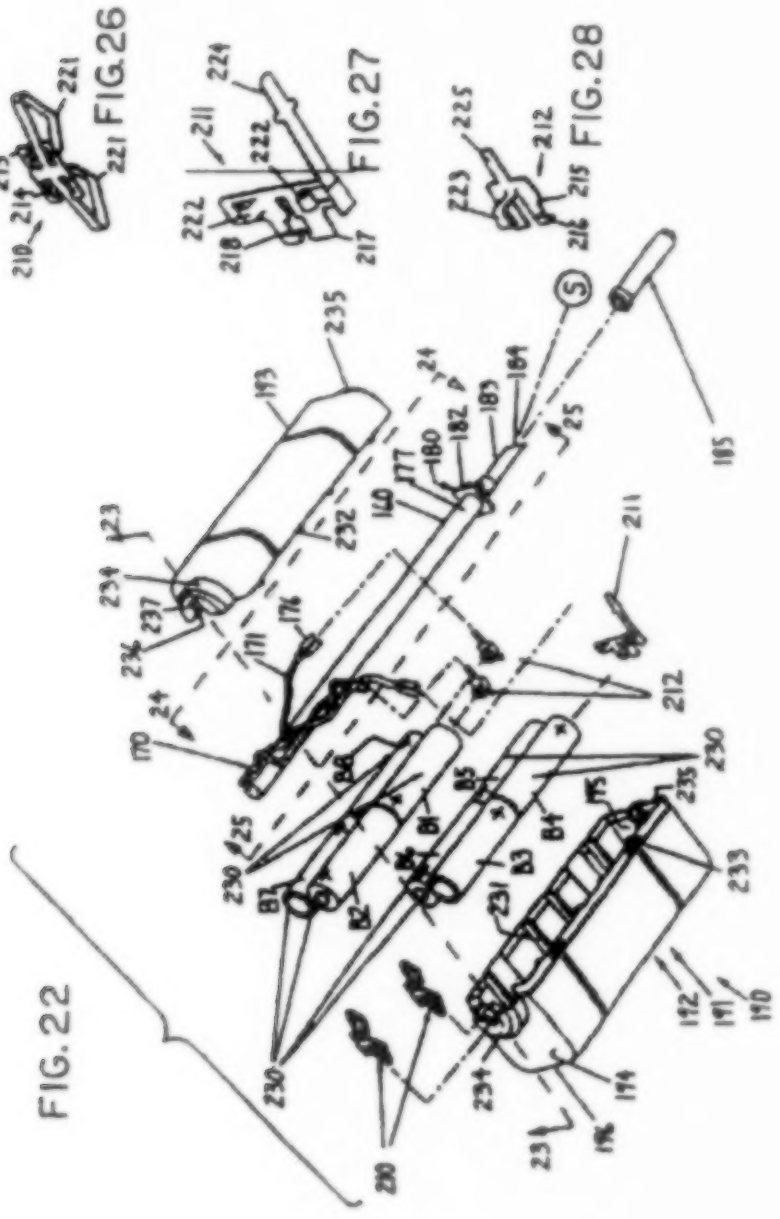
FIG.26
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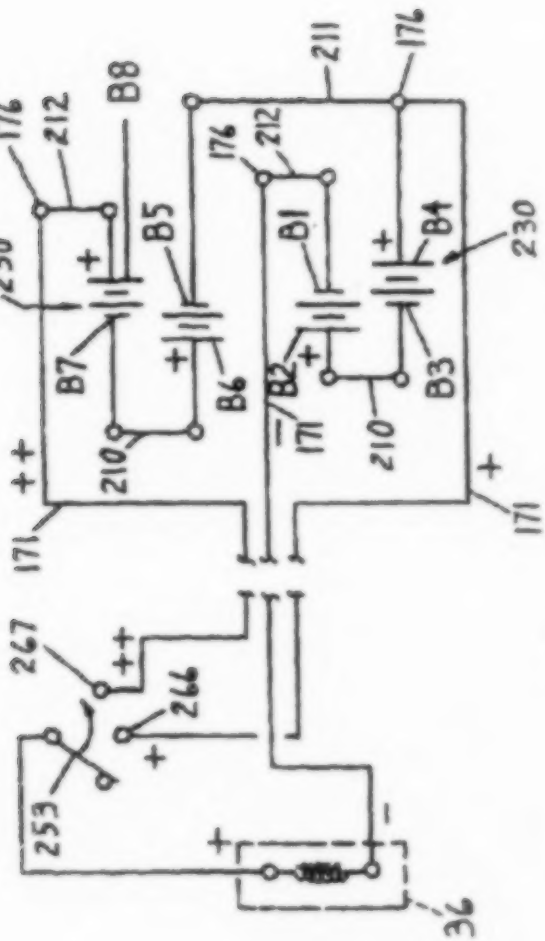
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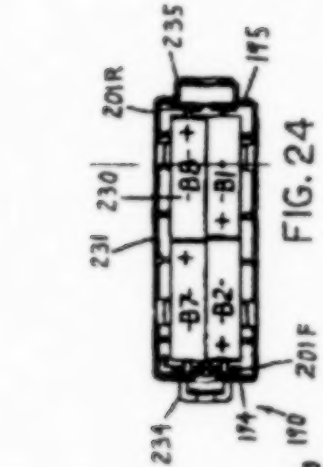
FIG. 22A



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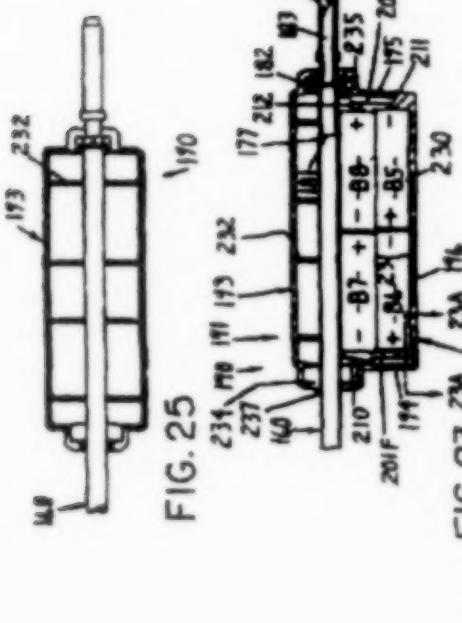


FIG. 23

FIG. 25

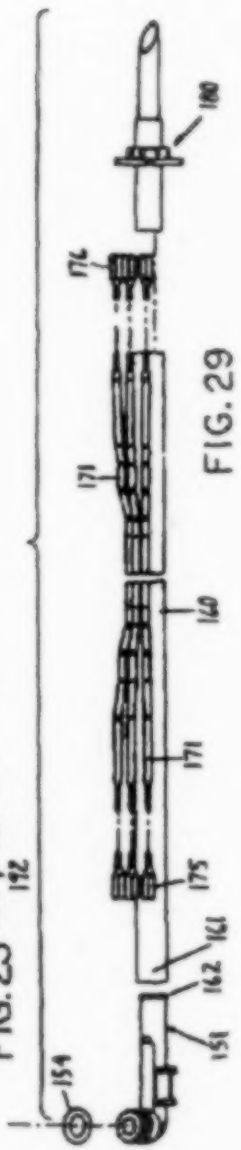
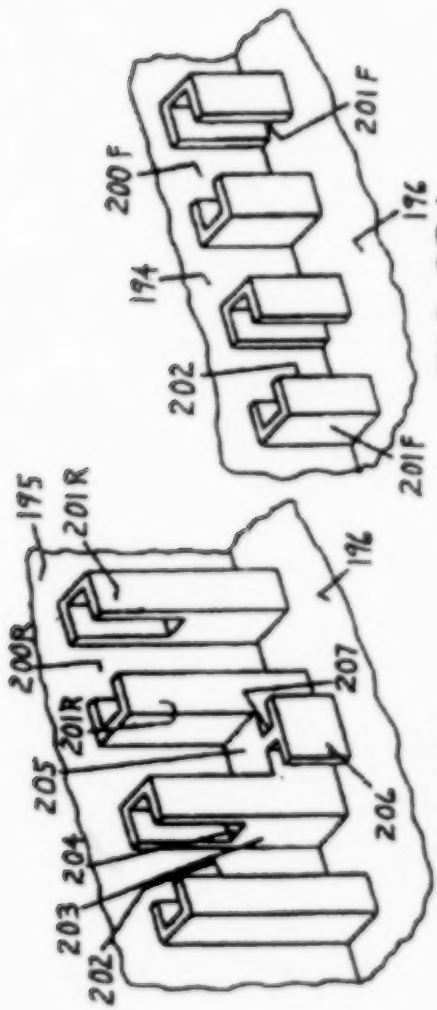


FIG. 29


200F
201F
196
194
202
201F
FIG. 23A
195
201R
200R
196
207
201R
205
204
206
203
202
FIG. 23B

SURGICAL/MEDICAL IRRIGATING HANDPIECE WITH VARIABLE SPEED PUMP, INTEGRATED SUCTION AND BATTERY PACK

This is a continuation of Ser. No. 09/460,705, filed Dec. 14, 1999, now U.S. Pat. No. 6,746,419, which is a continuation of Ser. No. 09/009,657, filed Jan. 20, 1998, now U.S. Pat. No. 6,022,329, issued Feb. 8, 2000 which is a continuation of Ser. No. 08/559,133, filed Nov. 17, 1995, now U.S. Pat. No. 5,718,668, issued Feb. 17, 1998 which is a continuation of Ser. No. 08/049,144, filed Apr. 19, 1993, now U.S. Pat. No. 5,470,305.

FIELD OF THE INVENTION

This invention relates to a surgical irrigation with a built in pulsing pump.

BACKGROUND OF THE INVENTION

Grulke et al U.S. Pat. No. 5,046,486, assigned to the Assignee of the present invention, discloses a surgical pulsed irrigation handpiece which produces a pulsed irrigation liquid output capable of loosening and floating debris at a surgical site for subsequent removal (as by suction). This prior pulsed irrigation handpiece has been on the market for several years and has proved generally effective for its intended use and hence has been popular in the surgical community.

However, in a continuing effort to improve on existing devices of this general kind, the present invention has been developed. As compared to the above-mentioned prior device, a pulsed irrigation handpiece embodying the present invention is producible at lower cost, produces sharper liquid pulse transients (particularly the pulse "off" transient), requires no con-

nection to any operating room power source (e.g. compressed air) or to an external pump, and instead is self-contained, requires only external connection to a irrigation liquid source (e.g. conventional irrigation liquid bag), provides better suction (when suction is required), is more compact, and is conveniently shaped to be held either as a pistol or a wand (by the handle or barrel).

Other objects, purposes and advantages of the invention will be apparent to those acquainted with apparatus as general kind upon reading the following description and inspecting the accompanying drawings.

SUMMARY OF THE INVENTION

A pulsed irrigation handpiece comprises pulsed irrigation liquid outlet means for applying liquid pulses to a surgical site, pump means reciprocatingly drivable for pumping pulses of irrigation liquid through said outlet means, powered drive means for reciprocatingly driving said pump means and housing means containing said pump means and drive means.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a pictorial view of a handpiece embodying the invention.

FIG. 2 is a laterally exploded pictorial view of the FIG. 1 handpiece.

FIG. 3 is an enlarged elevational view of the FIG. 1 handpiece with the leftward housing part removed.

FIG. 4 is a view similar to FIG. 3 but with the suction hose removed, the left drive unit shell part re-

moved and the drive unit exposed in central cross-section, such that FIG. 4 approximates a central cross-sectional view of the FIG. 1 handpiece.

FIG. 4A is an enlarged fragment of FIG. 4 detailing the rearward portion of the handle.

FIG. 4B is an enlarged fragmentary pictorial view, taken from the front, of the electrical contact support posts seen in FIG. 4A.

FIG. 4C is an enlarged fragmentary exploded pictorial view of the electrical contacts, associated with the FIG. 4B posts and associated electrical conductors from the battery supply.

FIG. 5 is an enlarged, exploded, pictorial view of the drive unit of FIG. 2.

FIG. 6 is a sectional view substantially taken on the line 6—6 of FIG. 5, and provides a top view of the bottom drive unit shell part of FIG. 5 (the rightward one of FIG. 2) with the drive components removed to show the interior configuration of that shell part.

FIG. 7 is a sectional view substantially taken on the line 7—7 of FIG. 5, and provides a view similar to FIG. 6 but showing the interior configuration of the other drive unit shell part (the upper one in FIG. 5 and leftward one in FIG. 2).

FIG. 8 is an enlarged central cross-sectional view of a tip unit usable with the handpiece of FIG. 2 and showing same installed in a pump unit shown in central cross-section substantially as in FIG. 4.

FIG. 8A is a reduced size, fragmentary, side elevational view of the apparatus of FIG. 8.

FIG. 8B is a pictorial view of the apparatus of FIG. 8A.

FIG. 9 is an end elevational view of the drive unit, taken from the right end in FIGS. 2 and 3.

FIG. 10 is a sectional view substantially taken on the line 10—10 of FIG. 5 and showing the drive unit with one shell part (the left one in FIG. 2 and top one in FIG. 5) removed to show the motor and transmission.

FIG. 11 is an elevational view of the drive train substantially taken on the line 11—11 of FIG. 10.

FIG. 12 is a central cross-sectional view substantially taken on the line 12—12 of FIG. 10.

FIG. 13 is a fragmentary cross-sectional view substantially taken on the line 13—13 of FIG. 10.

FIG. 14 is a cross-sectional view substantially taken on the line 14—14 of FIG. 10.

FIG. 15 is a sectional view substantially taken on the line 15—15 of FIG. 10.

FIG. 16 is an exploded pictorial view of the pump unit of FIG. 2 in an enlarged scale.

FIG. 17 is a front end elevational view of the pump unit of FIG. 16 taken substantially from the left side of FIGS. 2–4 and 16.

FIG. 18 is a central cross-sectional view of the pump unit of FIG. 17 taken substantially on the line 18—18 of FIG. 17.

FIG. 18A is a fragment of FIG. 18 showing the pump unit at the beginning of an intake stroke.

FIG. 18B is a fragment of FIG. 18 showing the pump nearing the end of an output pulse.

FIG. 18C is a fragmentary enlargement of FIG. 18 showing the valve member.

FIG. 19 is a fragmentary cross-sectional view showing the connection of the pump unit to the liquid supply hose.

FIG. 20 is a pictorial view of the electric power supply unit connected to the FIG. 2 handpiece.

FIG. 21 is a left end view of the FIG. 20 electric power supply unit.

FIG. 22 is an exploded pictorial view of the electric power supply unit of FIG. 20.

FIG. 22A is an electrical schematic of the FIG. 2 handpiece and FIG. 20 electric power supply unit.

FIG. 23 is a central cross-sectional view taken substantially on the line 23—23 of FIG. 22.

FIG. 23A is an enlarged fragmentary pictorial view of the support structure for battery contacts at the forward (left in FIG. 23) end of the electric power supply casing.

FIG. 23B is an enlarged pictorial view similar to FIG. 23A but showing the support structure for battery contacts at the rearward (rightward in FIG. 23) end of the power supply casing.

FIG. 24 is a sectional view substantially taken on the line 24—24 of FIG. 22 and showing the electric power supply unit with its top cover removed.

FIG. 25 is a sectional view substantially taken on the line 25—25 of FIG. 22 and showing the underside of the cover of the power supply casing.

FIGS. 26, 27 and 28 are enlarged pictorial views of battery contacts of FIG. 22.

FIG. 29 is an enlarged fragmentary pictorial view of an embodiment of the liquid supply and electric wiring harness of the apparatus of FIGS. 2 and 20 but showing a modification in the attachment of the electrical and liquid handling components.

In the following detailed discussion the terms "up", "down", "right" and "left", and variations thereon, refer to structural elements in their positions in specified drawing figures.

DETAILED DESCRIPTION

A pulsed irrigation handpiece 10 (FIGS. 1 and 2) embodying the invention comprises a hand-held housing 11 having a handle 12 and a barrel 13 which extends forward from the upper end of the handle 12 at about a 130° to 150° (here about 145°) angle thereto.

The housing 11 is hollow and, for convenience in assembling the handpiece 10, is constructed as later-

ally opposed concave left and right housing parts 14 and 15 (FIG. 2). The housing parts 14 and 15 are preferably molded rigid plastic elements held together rigidly by any convenient means, here comprising undercut snap fit tabs 16 protruding from the top and bottom edges of the right housing part 15 to snap over an interior edge flange (not shown) on the top and bottom edge of the left housing part 14. If desired, precise registry together of the two housing parts can be assisted by laterally projecting pins 20 distributed along the edges of one housing part (here the left housing part 14) piloted in holes 21 (FIG. 4) in the opposed edges of the other housing part (here 15). Upon completion of assembly of the handpiece 10, the two housing parts 14 and 15 may be adhesively bonded together. The handpiece is intended to be a disposable item and therefore access to the interior of the housing for purposes of repair is not needed.

Drive Unit

The drive unit 25 (FIGS. 2–15) is self contained in its own shell 26 (FIG. 2). For convenience in assembly, the shell 26 comprises two opposed concave shell parts 30 and 31 respectively disposed to the left and right in FIG. 2. The shell parts 30 and 31 are preferably of rigid molded plastics material. When the drive unit 25 has been assembled, as in FIGS. 2 and 9, the shell parts 30 and 31 are held fixedly together by any convenient means, here by resilient snap connection of generally U-shaped clips 32, molded in spaced relation along the perimeter edge of the shell part 31 which overlap the perimeter edge of the shell part 30 and snap over tabs 33 protruding therefrom, as seen in FIGS. 5–7. Precise location of the shell parts 30 and 31 with respect to each other is assisted by locator

pins 34 fixedly protruding from the shell part 31 and holes 35 in the opposed portions of the shell part 30.

A single conventional DC energizable electric motor 36 (FIGS. 4 and 5) is snugly housed in the space between the left and right (FIG. 2) shell parts at the rear (left in FIGS. 5–7, 10 and 12) thereof. The motor 36 is snugly axially located between the rear end wall and a transverse internal bulkhead 41 of the shell 26 (FIGS. 5–7, 10 and 12). The rear end wall 40 and bulkhead 41 have opposed parts in the left and right shell parts 30 and 31, as seen in FIGS. 6 and 7.

Rear and front bosses 42 and 43 respectively extend rearward and forward from the cylindrical casing 44 of the motor 36, as seen in FIGS. 10 and 12), and are supported in corresponding coaxial recesses 45 and 46 in the rear end wall 40 and bulkhead 41 respectively, so as to support the motor casing 44 with respect to the shell 26. A flat 47 on the rear boss 42 (FIG. 9) co-acts with a corresponding flat in the surrounding recess 45 to prevent rotation of the motor casing 44 with respect to the shell parts 30 and 31, such that the motor 36 is antirotationally fixed within the shell 26.

The drive unit 25 further includes a transmission 50 (FIG. 5) coaxial with and forward of the motor 36. The transmission includes a reciprocating link member 51 and is driven from the forward extending, rotating output shaft 52 of the motor 36. The shaft 52 extends coaxially forward through the front boss 43 (FIG. 12) of the motor 36.

The transmission 50 (FIGS. 5 and 12) includes a pinion gear 53 fixed on the motor shaft 52 for rotation

thereby, and a face gear 54 which, as seen in FIG. 12, underlies the pinion gear 53. The face gear 54 has a relatively large diameter central disk 56 carrying upward facing teeth 55 engaging corresponding teeth on the pinion gear 53 for rotation thereby. The face gear 54 includes a secondary pinion gear 57 fixed coaxially beneath the disk 56, and of substantially lesser diameter, which in turn drives a relatively large diameter output gear 60.

It will be understood that the pinion gear 53, face gear 54, secondary pinion 57 and output gear 60 are all provided with a full circumferential (360°) set of teeth, so that continuous rotation of the motor shaft 52 results in continuous rotation of the output gear 60. For convenience in drawing, some or all the gear teeth are not shown in various of the drawings, the toothed meshing connection of the gears therein thus being only schematically shown. See for example FIGS. 4, 10, 12, 13 and 14.

An output shaft 61 is fixed to and coaxially upstanding from the output gear 60 (FIG. 12) and fixedly rotatably drives an eccentric member 62 (FIGS. 5, 10 and 12) spaced above the output gear 60. In this embodiment, the output shaft is of rectangular cross-section to maximize its torque transmitting capability.

The eccentric member 62 comprises a radially extending disk 63 (FIG. 5) coaxial with the output shaft 61 and fixedly surmounted by an eccentric circular cylinder 64 eccentrically rotatable with the output shaft 61.

The link member 51 is generally T-shaped, as seen in FIG. 13, having a plate-like body 70 overlying the

disk 63 of the eccentric member 62 and lying at right angles to the output shaft 61, and further having a plate-like fork 71 fixed at the rightward (FIGS. 5, 10, 12 and 13) end of the plate-like body 70 and extending in a plane substantially parallel to the output shaft 61. The plane of the plate-like fork 71 is perpendicular to the intended direction of reciprocating movement of the link member 51. The body 70, at its end portion remote from the fork 71, has an oblong through opening 72 snugly radially receiving the rotating eccentric cylinder 64 of the eccentric member 62, as seen in FIG. 10. More particularly, the length direction of the oblong opening 72 extends parallel to the plane of the fork 71 and is of sufficient length to accommodate 360° rotation of the eccentric cylinder 64 without movement of the body 70 parallel to the plane of the fork 71. On the other hand, the width of the oblong opening 72, namely in a direction perpendicular to the plane of the fork 71, corresponds substantially to the diameter of the eccentric cylinder 64, providing a sliding clearance between the body 70 and eccentric cylinder 64, so that rotation of the eccentric cylinder 64 will result in reciprocation of the link member 51 in a direction perpendicular to the plane of the fork 71.

The plate-like body 70 includes a thickened rim 73 (FIG. 5) around the oblong opening 72 and may thus be said to form a yoke for coaction with the eccentric cylinder 64. The side edges of the body 70 are preferably also thickened to form parallel longitudinal guide rails 74 (FIG. 10).

The above discussed moving elements of the transmission 50 are located and movably supported within the shell 26 as follows. The face gear 54 has coaxial downward and upward (FIGS. 5–7, 10 and 12)

extending stub shafts 75 and 76 respectively rotatably supported in coaxial bearing bosses 80 and 81 respectively fixed on the opposing faces of the shell parts 31 and 30 (FIGS. 6, 7 and 12). Similarly, the output gear 60 and the eccentric member 62 have respective downward and upward extending stub shafts 82 and 83 coaxial with the output shaft 61 and rotatably supported in respective cylindrical bearing bosses 84 and 85 in the respective shells 31 and 30 (FIGS. 5–7 and 12). The link member 51 is slidably guided for reciprocation in a notch 90 (FIGS. 5 and 7) in the peripheral wall 91 of the left (upper in FIG. 5) shell part 30. The notch 90 has parallel opposed guide faces 92 (FIG. 7) spaced apart to snugly slidably guide therebetween the opposite guide rails 74 of the link member 51, and thus spaced at substantially at the maximum width of the link member. The thickness of the link member is guided for reciprocation between the peripheral edge 93 of the right (lower in FIG. 5) shell 31 and the width wall 94 (FIGS. 5 and 7) of the other shell part 30.

The central length axis LA (FIG. 10) of the link member intersects the central length axis MA of the motor shaft 52 at the axis SA of the output shaft 61 and stub shaft 83 (FIGS. 10 and 12), at an angle equal to the angle between the central length axis of the handle 12 and barrel 13 of the housing 11. Moreover, the length axes of the handle and barrel also intersect at the axis SA of the output shaft 61 when the drive unit 25 is installed in the handpiece housing 11 as hereafter discussed. In effect then, the link member longitudinal axis LA and motor shaft axis MA define the length axis of the barrel 13 and handle 12, respectively, when the drive unit 25 is installed in the handpiece housing 11.

The drive unit 25 is located within the handle 12, as follows. As seen in FIGS. 3 and 4, transverse ribs 95 are molded into the interior surface of the handle 12 at opposing locations in the left and right housing parts 14 and 15 (FIGS. 2–4). For drawing convenience, only the ribs in the right housing part 15 are shown, the ribs in the left housing part 14 being compatible. The ribs 95 locate the drive unit 25 in the rightward/leftward direction in FIG. 2. Further, the drive unit shell bosses 84 and 85 (FIG. 5) protrude sideways from the drive unit shell and are pivotally received in corresponding hollow cylindrical bosses, one of which is shown at 96 in FIG. 2, and which extend toward each other from the interior of the left and right housing parts 14 and 15. The hollow cylindrical boss 96 of the left housing part 14 is not shown but is opposed to and compatible with the housing part 96 shown in the right housing part 15 of FIG. 2. The drive unit 25 is thus, except for the lateral positioning defined by the ribs 95, pivotally located within the handpiece housing 11 and is thus capable of some pivotal floating in the housing to achieve proper alignment of the longitudinal movement axis LA (FIG. 7) of the link member 51 with respect to the barrel 13 and a pump unit 100 (FIGS. 2–4 and 16–18) located in the barrel 13 as hereafter discussed.

Pump Unit

Turning now to the pump unit 100, attention is directed to FIGS. 2–4 and a6 18. The pump units includes a bellows 101 including an axially expandable and contractable, reciprocating, bellows wall 114 (FIG. 18) and a forwardly extending, rigid annular flange wall 102. Such flange wall 102 is loosely telescoped over a rigid, rearwardly extending annular

flange 103 of a rigid, forwardly extending coaxial bellows housing 104.

The bellows 101 and bellows housing 104 are preferably of molded plastics material. A resilient O-ring 105 (FIGS. 16 and 19) is snugly radially disposed between the radially opposed, axially extending annular flanges 102 and 103, to create a fluid seal therebetween and hence between the bellows 101 and bellows housing 104, to prevent fluid leakage therebetween. The bellows 101 and bellows housing 104 have respective axially spaced radially extending steps 106 and 107 joined to the respective annular flanges 102 and 103 and axially spaced apart at a distance substantially greater than the diameter of the O-ring 105, as seen in FIG. 19. The axial extending flanges 102 and 103 and radially extending steps 105 and 106 define an annular chamber 110 in which the O-ring 105 is axially loosely, and radially snugly and sealingly, disposed. Note that the radially opposed surfaces of the axially extending annular flanges 102 and 103 are cylindrical, such that neither has an annular groove in which the O-ring seats. Thus, the O-ring is free to roll on the radially opposed cylindrical surfaces of the axially extending flanges 102 and 103 and the O-ring 105 does not significantly interfere with axial separation of the bellows 101 and bellows housing 104 from each other.

Instead, such axial separation is prevented, as hereinafter further discussed, by a forwardly-rearwardly (leftwardly-rightwardly in FIG. 2) spaced pair of ribs 111 (FIG. 2) extending radially inward from the interior wall of the right housing part 15 and a corresponding, laterally opposed pair of mirror imaged ribs (not shown) extending laterally inward from

the interior wall of the left housing part 14. Such ribs 111 are also schematically indicated in FIG. 18.

The rear (right in FIG. 19) end of the bellows housing axial flange 103 abuts the radially extending step 106 of the bellows 101 and the forward (leftward in FIG. 19) end of the bellows axial flange 102 axially abuts a radial flange 112 which extends radially outward from and forwardly from the bellows housing step 107. The forward end of the bellows axial flange 102 thus radially overlaps the bellows housing step 107 in snug but axially slidable relation thereto. A small forwardly extending annular rib 113 protrudes forwardly from the bellows radial step 106 toward the O-ring 105 to prevent rearward escape of the O-ring 105 from the space between the axially extending flanges 102 and 103, in the event of slight axial shifting of the bellows 101 and bellows housing 104 away from each other.

The above mentioned radially inward extending ribs 111 of the handpiece housing 11 snugly axially oppose and sandwich therebetween the bellows radial step 106 and bellows housing radial flange 112 to positively prevent axial separation of the bellows 101 from the bellows housing 104, when the pump unit 100 is installed in the housing 11.

The above-mentioned bellows wall 114 extends rearward from the inner periphery of the radially extending annular step 106 of the bellows 101 (FIG. 18) and consists of an axially collapsible and extensible, flexible, wave cross-section, peripheral wall 114. The bellows wall 114 surrounds an axially expansible and contractible pumping chamber 115. At the rear end of the bellows 101, a radially extending drive end wall

116 closes the rear end of the bellows wall 114 and pumping chamber 115. A stub 120, having a radially enlarged head 121, is fixed to and extends coaxially rearwardly from the drive end wall 116.

To axially reciprocatingly drive (repetitively axially contract and expand) the bellows 101, the above discussed link member 51 (FIG. 5) of the drive unit 25 has its fork 71 provided with a central, radially opening, generally U-shaped slot 122 (FIGS. 11–13). The slot 122 divides the fork 71 into a pair of tines 123 (FIG. 11). The slot 122 opens leftwardly in FIG. 2, namely away from the rightward housing part 15 and toward the leftward housing part 14. Thus, with the drive unit 25 located in the right housing part 12 as seen in FIG. 3, the pump unit 100 can be inserted into the rightward housing part 15, with the stub 120 (FIG. 18) inserted in the slot 122 of the fork 71 (FIG. 11) so as to trap the tines 123 axially between the drive end wall 116 and head 121 of the bellows 101, as generally indicated in FIGS. 3 and 4. To prevent the bellows stub 120 from accidentally radially escaping out the open end of the slot 122 in the fork 71, the central portion 124 (FIG. 11) of the slot 122 is undercut by inward tapering of an intermediate portion 125 of the slot 122 as seen in FIG. 11. The tapered portion 125 of the slot 122 (FIG. 11) defines a snap fit detente for resiliently trapping the bellows stub 120 in the drive unit slot 122. Thus, to install the bellows stub 120 in the slot 122, the bellows stub 120 must be resiliently forced through the tapered portion 125 of the slot 122 and upon passing the latter, the stub resiliently snaps into the central portion 124 of the slot. The inner ends of the tapered portion 125 of the slot resiliently maintain the stub radially inboard thereof, in the central portion 124 of the slot 122.

The stub **120** and hence the bellows **101**, and indeed the entire pump unit **100**, is thus freely rotatable about its length axis with respect to the fork **71**, so that the circumferential orientation of the drive unit **25** and the pump unit **100** is determined by the location thereof in the housing. The drive unit **25** and pump unit **100** are thus, to an extent, free to circumferentially float with respect to each other, about the connection of the stub **120** and fork **71**, without interfering with the circumferential location of the drive unit **25** and pump unit **100** in the housing **11**. Further, the edges of the slot **122**, in particular of the central portion **124** thereof, are rounded in cross-section, as is the stub **120**, to permit a modest amount of angular adjustment between the length axes MA and LA of the drive unit **25** and pump unit **100** and to allow the drive unit **25** and pump unit **100** to easily settle into their proper operating positions in the housing **11**.

A cylindrical plug **126** is coaxially fixed to the interior side (left side in FIG. **18**) of the bellows drive end wall **116** by a coaxial, rearward extending, undercut pin **127** snap fitted in a forwardly (leftwardly in FIG. **18**) opening recess in the stub **120**. The plug **126** has a diametral slot **130** opening forward from its front end and which faces forward toward a resilient valve member **131** (FIGS. **16** and **18**) to maintain liquid communication between the central and radially outer portions of the pumping chamber **115**.

The bellows **101** is thus a single element which carries out four different functions, namely sealing at the forward end, changing the pump chamber size in the middle thereof, the rearend acts as a piston and as a drive point. In addition, the front annular flange **102**

helps locate the pump unit with respect to the housing barrel.

The pump unit **100** further includes a valve member **131**, which is a one piece member of suitable resilient material and which by itself constitutes the entire moveable inlet and outlet valve system for the pump unit **100**. More particularly, the valve member **131** comprises a short tubular central portion **132** (FIG. 18) which coaxially connects a forward (leftward in FIG. 18) tapering, duck bill type, outlet valve **133** and a rearwardly and radially outwardly extending umbrella type, inlet valve **134**. The umbrella valve **134** is annular and has a central opening **135** which communicates coaxially from the pumping chamber **115** in the bellows **101** forwardly through the tubular central portion **132** and outlet duck bill valve **133** of the valve member **131**.

The bellows housing **104** comprises a rear (right in FIGS. 18 and 18C) facing recess having a perimeter defined by the annular flange **103** of the bellows housing **104** and a rear facing radial wall **136** which defines the front end of the pumping chamber **115**. The umbrella valve **134** lies coaxially in the resulting recess **103, 136**. The forward facing perimeter **137** of the umbrella valve **134**, in its closed condition shown in FIGS. 18 and 18C, presses forward against the radial wall **136** to seal thereagainst. The valve member **131** is held against the right (rearward) movement away from the bellows housing wall **136** by axial interference between a rightward facing, radially outward extending, annular step **140** (FIG. 18C) at the rear (right) end of the duck bill valve **133**, and a radially inward extending, leftward facing, annular flange **141** of the bellows housing **104**. The radially inward di-

rected, annular flange **141** is axially interposed between, and forms a port **142** between, the rear facing recess **103, 136** and a coaxial, forwardly extending, cylindrical, irrigation liquid outlet, discharge, conduit **143** (FIGS. **18** and **18C**). The tubular central portion **132** of the valve member **131** extends snugly axially through the port **142**.

To install the valve member **131** in the bellows housing **104**, the tapered outlet duck bill valve **133** is pushed forward through the port **142**, the bellows valve step **140** snaps forwardly (leftwardly in FIG. **18C**) past the bellows housing flange **141**, and the sealing perimeter **137** of the umbrella valve **134** is thereby pulled forwardly resiliently against the rearward facing bellows housing wall **136**, leaving the valve member **131** with its duck bill valve **133** and umbrella valve **134** both in their closed condition shown in FIGS. **18** and **18C**.

The bellows housing **104** further includes an annular liquid jacket **144** (FIGS. **18** and **18C**) surrounding the rear portion of the liquid outlet conduit **143** and defining radially therebetween an annular liquid inlet chamber **145** (FIGS. **18, 18C** and **19**). The inlet chamber **145** communicates between a radial inlet port **146** (FIGS. **16** and **19**), which opens radially outward through the side of the bellows housing **104**, and an annular space **147** (FIG. **18C**). The annular space **147** is bounded by the forward face **150** and tubular central portion **132** and sealing perimeter **137** of the umbrella valve **134** and the radial face **136** of the recess **103, 136** of the bellows housing **104**.

Thus, a rightward pullback of the bellows head **121** axially expands the bellows, from its FIG. **18A** posi-

tion towards its FIG. 18 position. This reduces the pressure within the bellows. This in turn keeps the duck bill valve 133 closed and pulls the sealing perimeter 137 of the umbrella valve 134 rightwardly away from the bellows housing recess radial wall 136 and draws liquid from the port 146 through the annular inlet chamber 145, around the perimeter 137 of the open umbrella valve and into the interior of bellows.

On the other hand, a leftward push forward of the bellows head 121 axially compresses the bellows from its FIG. 18 position toward its FIG. 18B position and raises the pressure in the bellows, to close the umbrella valve 134 and open the duck bill valve 133 and force a pulse of liquid out of the bellows forwardly through the duck bill valve 133 and liquid outlet conduit 143.

Irrigation liquid is drawn to the inlet port 146 of the bellows housing 104 through an elbow 151 (FIG. 19). The outlet end 152 of the elbow and the inlet port 146 are cylindrical, with the elbow outlet end 152 being a snug axially sliding fit in the inlet port 146. An axially elongate, annular groove 153 in the outer periphery of the elbow outlet 152 houses a seal ring, here an O-ring, 154 which bears sealing and rollingly on the radially opposed and surrounding surface of the inlet port 146 to prevent liquid leakage out of the elbow 151 at its interface with the inlet port 146. The elbow 151 is not mechanically interlocked with the inlet port 146 but can slide in and out with respect thereto. The elbow 151 is held in place with its outlet end 152 sealingly within the port 146 by bearing of a portion 155 (FIG. 4) of the handpiece housing barrel 13 against the outboard surface 156 of the elbow 151, with the pump unit installed in the handpiece housing

11. The elbow 151 here fixedly carries a pair of parallel fins 157 (FIGS. 16, 17 and 19). The fins 157 extend radially from the rear inlet end portion of the elbow 151 and axially sandwich therebetween the flanges 106 and 112 of the bellows 101 and bellows housing 104, at least to help the housing ribs 111 (FIG. 18) fins 157 prevent axial separation of the bellows and bellows housing. The housing ribs 111 and fins 157 are more or less evenly circumferentially located around the bellows 101 and bellows housing 104.

An elongate flexible irrigation liquid supply hose 160 (FIGS. 2, 4, 16, 17, 19, 22, 23, 25 and 29) has a forward end 161 which telescopes sealing and fixedly over the rear end 162 of the elbow 151 as seen in FIGS. 19 and 29. Although an annular barb is shown at 162 (for example in FIG. 19) a barbless, cylindrical end 162 is satisfactory. In the assembled handpiece, the irrigation liquid hose 160 extends rearward from the elbow 151 (FIG. 4) in the barrel 13 of the housing and angles downwardly and rearwardly along the bottom of the handpiece handle 12 to exit rearwardly and downwardly through a hole 163 (FIG. 2) in the bottom end wall 164 of the handpiece housing 11. A clamp plate 165 (FIGS. 2, 3 and 4) of bent cross-section has a perimeter groove 166 for receiving the edges of the hole 163 in the housing bottom end wall 164, such that the clamp plate 165 is trapped in and partly closes the hole 163 in the bottom end 164 of the housing handle 12 when the housing is fully assembled. A notch 167 (FIG. 2) in the rightward end of the clamp plate 165 permits exit therethrough of irrigation liquid supply hose 160 from the handpiece housing 11 and snugly and frictionally grips such hose, without crushing or collapsing it, so that such hose 160 cannot easily be pulled out of the housing 11 or off the elbow 151.

The irrigation liquid hose 160, the inlet line, integrally therewith, a smaller diameter rib 170 (FIGS. 2, 16, and 17) A plurality (here three) insulated electrical conductors (wires) 171 have intermediate portions contained within and extending the length of the rib 170. Forward end portions of the insulated wires 171 emerge from the forward end of the rib 170 and carry conventional electrically conductive connectors 175. The forward end of rib extend through the notch 167 (FIG. 2) and ends just inside the bottom portion of the handle of the housing 11, as seen in FIG. 4. The forward ends of the conductors, carrying the connectors 175, extend into the lower portion of the handpiece handle 12. Thus, as apparent from the below description, rib 170 functions as a cable through which conductors 171 extend from the battery pack to the handpiece housing 11.

The insulated electrical conductors 171 extend along the length of the central portion of the liquid supply hose 160 and have rear ends provided with respective electrically conductive connectors 176 (FIGS. 22 and 29), such that electric current can flow from a given rear connector 176 through its corresponding insulated electrical conductor 171 and to its corresponding front electrically conductive connector 175 in a conventional manner. Short rear portions of the conductors 171 are loose and moveable with respect to the liquid supply hose 160 as seen in FIGS. 22 and 29.

The electrical connectors 175 and 176 are conventional crimp type connectors.

Instead of being molded in or otherwise constrained within the generally circular cross section rib 170 in FIG. 2, the elongate central portion of the insu-

lated electrical conductors 171 may be fixed side by side, in a flat array, to the outside of the liquid hose 160, as shown in FIGS. 22 and 29, and such can be accomplished by adhesive bonding or by any other convenient means.

The hose 160, 170 thus serves the dual use of conveying both irrigation liquid and electric operating power.

The length of the central portion of the liquid hose 160, to which the insulated conductors 170 are fixed, preferably extends several feet (for example 8 to 10 feet) from the handpiece 10. The rear end 177 (FIGS. 22 and 23) of the liquid hose is here provided with a fitting 180 of hollow tubular construction open to axial liquid flow therethrough. The fitting 180 comprises a forward end portion 181 (FIG. 23) fixed sealingly telescoped in the rear end 177 of the liquid hose 160, a square central flange 182 (FIG. 22) and a rear end portion (or "spike") 183 having a sharpened tip 184. The tip 184 is capable of conventional insertion into a conventional source S (FIG. 22) of irrigation liquid, for example a conventional supply bag, for conveying irrigation liquid therefrom forward into the hose 160. The square flange 182 prevents rotation of the fitting 180 in the casing 191, which helps when removing the spike 183 from the liquid supply bag. In the embodiment shown, the rear end portion 183 is covered by a protective cap 185 prior to use so that the sharpened tip 184 will not accidentally be dulled.

Thus, the length of the liquid supply hose 160 allows the irrigation liquid source S to be located at a distance from the handpiece and thus out of the way

of the surgical personnel at the operating table where the handpiece **10** is to be used.

Electrical Power Supply Unit

To provide operating electrical power to the motor **36**, a compact, self contained electrical supply unit **190**, a battery pack, (FIGS. **20–25** is fixed on the rear portion of the liquid hose **160**. The power supply unit is thus located remotely from the handpiece **10**, adjacent to the source S of irrigation liquid.

The power supply unit **190** comprises a casing **191** preferably of rigid molded plastics material. The casing **191** here comprises a relatively deep, substantially rectangular pan **192** (FIG. **2**) whose top (as oriented in FIGS. **22** and **23**) is fixedly closed by a cover **193**. The pan **192** has front and rear end walls **194** and **195** (FIGS. **23**, **23A** and **24**) having fixed upward opening slots **200** each defined by a laterally spaced, opposed pair of U-shaped flanges **201** (FIGS. **23A** and **23B**). The slots **200** are undercut in that each has a mouth **202** laterally narrower than the remainder of the slot **200** and communicating between the remainder of the slot **200** and the interior cavity of the pan **192**. The undercut slots **200** are of constant cross-sectional size and shape vertically (i.e. into and out of the page in FIG. **24** and up and down in FIG. **23**).

For convenient reference in the drawings, the reference numerals **200** and **201** are suffixed, so that the undercut slots and U-shaped flanges on the front pan wall **194** are indicated by the reference characters **200F** and **201F** and the undercut slots and U-shaped flanges on the rear pan wall **195** are indicated at 200R and 201R.

The U-shaped flanges **201F** defining the slots **200F** on the forward end wall **194** start substantially from the pan bottom wall **196** and extend a bit less than half way up the front end wall **194**.

On the other hand, the U-shaped flanges **201R** of the slots **200R** on the rearward end wall **195** of the pan are spaced above the bottom wall **196** of the pan upon respective block-like pillars **203** which define an up-facing bottom **204** for each of the U-shaped flanges **201R** on the rear pan wall **195**.

Rising from bottom wall **196** of the pan between the two central pillars **203** to a height below the bottoms **204** of the slots **200R** thereof, is a central block **205** from which forwardly extends, along the pan bottom wall **196**, a T-shaped flange **206** (FIG. **23B**) of constant cross section vertically and defining a pair of vertically open and laterally oppositely opening grooves **207** disposed immediately forward from the two central pillars **203** on the rear pan wall **195**.

Two such undercut slots **200F** are spaced symmetrically side by side on the front pan wall **194**. Similarly, and at the same effective lateral spacing, two such slots **200R** are spaced laterally side by side on the pan rear wall **195**.

Springy, electrically conductive sheet metal battery contacts of three different kinds are indicated at **210** and **211** and **212** and FIGS. **26**, **27** and **28** respectively.

A pair of such contacts **210** are provided and each comprises a generally rectangular foot **213** adapted to snugly slide down into a respective undercut slot **200F**

at the pan front wall **194**. Each foot **213** is provided with resilient toes **214** angled out of the plane of the foot **213** and adapted to bite against the interior of the corresponding undercut slot **200F** to fix the corresponding battery contact **210** in place therein.

Similarly, each of a pair of battery contacts **212** (FIG. **28**) has a resilient fork-shaped foot **215** adapted to fit snugly and slidingly down into the corresponding undercut groove **200R** at the rear wall **195** of the pan **192** and with springy toes **216** for fixedly gripping the interior of the corresponding undercut slot **200R**.

In a generally similar manner the single, low speed battery contact **211** (FIG. **27**) has a resilient U-shaped foot **217** for sliding down over the T-shaped flange **206** (FIG. **23B**), with springy toes **218** bent out of the plane of the foot **217** for bitingly engaging the walls of the grooves **207** of the T-shaped flange **206**.

Each of the battery contacts **210**, **211** and **212** thus slides with its corresponding foot into the desired location with respect to the grooves **200F**, **200R** and **207** and locks fixedly therein. This is generally indicated in FIGS. **22–24**. The battery contacts **210**, **211** and **212** have respective resilient fingers **221**, **222** and **223** (FIGS. **26**, **27** and **28** respectively), two each for the battery contacts **210** and **211** and one each for the battery contacts **212**. Such fingers **221**, **222** and **223** protrude from the respective slots **200F**, **200R** and **207** into the interior of the pan **192** for electrically contacting batteries **230** (FIG. **22**) to be housed in the pan **192**. Further, the battery contact **211** and each of the battery contacts **212** (FIGS. **27** and **28** respectively) have an upstanding terminal (**224** and **225** respectively) of simple rectangular shape for releasable tele-

scoped engagement within a respective one of the connectors **176** at the rear ends of the three insulated electrical conductors **171** (FIG. **22**).

Turning now to the arrangement of the batteries **230** within the pan **192**, one embodiment according to the invention advantageously uses batteries of a kind widely available in retail stores, namely AA size alkaline batteries. In addition to their wide availability to the public, these batteries advantageously are inexpensive, have a long shelf life and provide full operating voltage until almost fully discharged. In the embodiment shown, eight such batteries **230** are provided and are individually indicated at **B1**, **B2**, **B3**, **B4**, **B5**, **B6**, **B7** and **B8**. As shown in FIGS. **22–24**, ribs **231** extending circumferentially within the pan **192** cradle the batteries **230** fixedly but removably within the pan **192**. The polarity of the eight batteries is indicated by "plus" signs marked thereon. As seen in the drawings, the batteries **230** are arranged in four rows of two head-to-tail batteries each. Four of the batteries **230** lie in the bottom (FIGS. **22** and **23**) of the pan in two rows of two each and the remaining four batteries **230** lie on top of those.

The ends of the battery rows bear variously on the above discussed battery contacts **210**, **211** and **212** as generally indicated for example in FIG. **22** and also in the schematic circuit drawing in FIG. **22A**. More particularly, the four batteries **B1**, **B2**, **B3** and **B4** defining a vertical plane nearest to the viewer in FIG. **23** are connected in series from the near connector **212** leftwardly through the top row of batteries, down through the near upstanding connector **210** and thence rightwardly through the bottom pair of batteries to the lower rear connector **211**. The remaining

four batteries **B5–B8** are arranged in a vertical plane behind above-mentioned batteries **B1–B4**. More particularly, the batteries **B5–B8** connect in series from the far side of the lower rear connector **211** forwardly (leftwardly in FIG. **22**) to the far connector **210**, upwardly therethrough, and then rearwardly back to the far upper connector **212**.

The cover **193** (FIGS. **23** and **25**) has plural, laterally extending, depending ribs **232** (FIGS. **23** and **25**) intended to seat upon the uppermost batteries **B1, B2, B7** and **B8** and fix the batteries **B1–B8** in the pan with the cover **193** fixed in its normal closed position atop the pan **192**. The cover is fixedly securable atop the pan by any convenient means, such as snap fit connectors, a portion of which are generally shown in **233** in FIG. **22**, and generally like those discussed above with respect to the handpiece housing **11**, as at **16**, and as generally discussed with respect to the drive unit shell **26**, as at **32, 33**.

The aforementioned rear end **177** of the hose **160** extends through the casing **191** along the horizontal parting plane between the pan **192** and cover **193**, and so lies close adjacent the topmost batteries **B1, B2, B7** and **B8**.

Hollow front and rear bosses **234** and **235** (FIGS. **23** and **25**) extend forward and rearward respectively, from the casing **191**. At the parting plane between the pan **192** and cover **193**, the bosses **234** and **235** are notched (for example at **236** in FIG. **22**) for extension therethrough of the rear end **177** of the liquid hose **160**. The rear hollow boss **235** is sized and shaped to receive radially therein the square flange **182** (FIG. **23**) on the rear end of the liquid hose **160**, and thereby

axially fix the rear end of the liquid supply hose **160** within the casing **191** and nonrotatably fix the fitting **180** to the battery casing **191**. The notch **236** in the front boss portion **234** on the cover **193** is indented by one or more small recesses **237** for receiving axially therethrough the rib **170** containing the insulated electrical conductors **171**, whose rear end connectors **176** are respectively fixed to the terminals **224** and **225** of the battery contacts **211** and **212**.

Trigger Unit

The handpiece **10** further includes a trigger unit **240** (FIGS. **2–4**) for controlling actuation of the motor **36** and, by extension, pump unit **100**. The trigger unit **240** comprises a generally L-shaped trigger member **241** (FIGS. **2**, **4** and **4A**), that functions as a control switch, and that comprises an elongate trigger lever **242**. The upper, forward (leftward in FIGS. **2** and **4**) end of the trigger lever is pivoted by laterally extending integral pins **243** pivotally receivable in suitable holes in laterally opposed bosses (one of which is shown in FIG. **2**) in the opposed lower edges of the housing parts **14** and **15**, near the rear end of the barrel **13**. Snapping together of the two housing parts **14** and **15** thus captures the pivot pins **243** and pivotally mounts the trigger with respect to the handpiece housing.

The trigger lever **242** includes a transverse ridge **245** (FIG. **4**) near to but spaced rearwardly from the pivot pins **243** and facing the underside of the barrel **13** and adapted to bear on the underside thereof in the manner of a fulcrum. By far the major length **246** of the trigger lever **242** is to the rear (right in FIG. **4**) of the fulcrum ridge **245**. This rearward trigger part **246**

is relatively rigid in the portion thereof spaced at least somewhat to the rear of the fulcrum ridge 245. Such rigidity is assisted by a forward facing longitudinal reinforcement rib 247 extending rearward along the front face of the trigger lever 242 from a point near the fulcrum ridge 245. The front of the trigger lever 242, to the rear of the fulcrum ridge 245 is, in the embodiment shown, provided with transversely extending ribs 248 to provide the user with a non-slip grip of the trigger lever 242.

The trigger lever 242 is bendable near the fulcrum ridge 245, both to the front and rear thereof, in a resilient manner. In this way, the resilience of the trigger lever tends to hold it in its forward, inactive position shown in FIG. 4, with the fulcrum ridge 245 bearing on the underside of the handpiece barrel 13. On the other hand, when the user grips the handle 12 and squeezes the trigger lever 245 toward it, in the direction indicated by the arrow TA in FIG. 4, the trigger lever bends in the region of the fulcrum ridge 245, tending to straighten from its relaxed convexly forwardly curved configuration of FIG. 4, so that the rear face of the trigger lever can be pulled into the dotted line position 242P, substantially against the front face of the handle 12. Upon release of the trigger by the user, the natural resilience of the trigger lever 242 unbends it back to its solid line forward position shown in FIG. 4. Accordingly, the trigger naturally returns forward to its non-operative position without need for a separate return spring.

The trigger arm 251 fixedly carries a thumb 250 (FIG. 4A) intermediate it ends in the housing handle 15 and which interferes with the housing wall adjacent the hole 252, to prevent the resilient restoring force of

the trigger lever 242 from pulling the trigger arm 251 leftwardly (FIG. 4A) out of the housing handle 12.

A plank-like switch contact support arm 251 (FIGS. 2, 4 and 4A) protrudes substantially at a right angle from the rear, or bottom, end of the trigger lever 242 and extends upwardly and rearwardly (in FIG. 4) into the lower portion of the handle 12, loosely through a hole 252 (FIG. 4A) in the opposing bottom wall of the handle. A plate-like electrically conductive contact blade 253 fixedly extends through the thickness of the arm 251, and has a front portion exposed towards said motor and a rear portion exposed toward the bottom end 164 of the handpiece handle.

A pair of rectangular posts 255 and 256 protrude fixedly into the interior of the handle 12 from the inside of the right housing part 15, about midway between the drive unit 25 and the housing bottom end 164 (FIGS. 4A and 4B). Each post 255 and 256 includes a T-shaped flange 260 extending substantially forward toward the drive unit 25. Each T-shaped flange 260 defines a pair of oppositely facing grooves 261 (FIG. 4C).

Electrically conductive, spring-like metal contacts 262 and 263 (FIGS. 4A and 4C) each have a substantially U-shaped foot 264 for reception on the T-shaped flange 260 of the corresponding posts 255 and 256. The contacts 262 and 263 further each have a substantially rectangular, projecting terminal 265 for telescopic fixing thereon, in electrically connected relation, a corresponding one of the front connectors 175 of the three insulated electrical conductors 171. The electrical contacts 262 and 263 further have respective, generally L-shaped, plate-like, flexible contact

leaves 266 and 267 (FIG. 4C). The contact leaves 266 and 267 extend toward the drive unit 25 as seen in FIG. 4A.

Protruding rearwardly from the motor 36 are a pair of electrically conductive contacts 270 and 271 (FIGS. 4A and 9). The contact 271 is a conventional terminal (like those at 224, 225 and 265) for receiving one of the front connectors 175 in fixed and electrically conductive relation thereon.

In contrast, the contact 270 is an elongate, springy rectangular piece, bent intermediate its ends in dog-leg fashion, and angling from the rear end of the motor 36 rearwardly and somewhat rightwardly (in FIG. 4A) to a free end portion spaced near the contact leaves 266 and 267.

Gradual pressing of the trigger lever 242 toward the handle housing (rightwardly in FIGS. 4 and 4A) moves the arm 251 and hence the contact blade 253 progressively further into the handle 12 through a series of positions, three of which are indicated in broken lines at 253A, 253B and 253C in FIG. 4A.

The free (rightward in FIG. 4A) end of the arm 251 is beveled at 272 to help it ride over the contacts 266 and 267 as the trigger lever 242 is sequentially squeezed more and more toward the handle 12. The arm 251 is progressively resiliently bent, like a leaf-spring, as its free end rides over the fixed contacts 266 and 267, to firmly press its contact blade 253 against the latter.

Thus, as the trigger lever 242 is pressed toward the handle 12, the beveled free end of the arm 251

rides over the contact leaf **266** past its dotted line position **253A** and toward its dotted line position **253B**. As the free arm end approaches position **253B**, the contact blade **253** slides into electrical contact with the contact leaf **266** and the motor contact **270** to establish electrical connection therebetween. The motor contact **270** resiliently bends to allow continued travel of the contact blade **253** and arm **251** further into the handle, as indicated in dotted line at **270B**, and to press firmly against the contact blade **253**. Given only a light pull on the trigger lever **242**, the arm **251** and contact blade **253** tend to stop in the position indicated in dotted lines at **253B**, by reason of the free end of the arm **251** colliding with the contact leaf **267**. In this "B" position, electric current is fed to the motor **36** only from half the battery collection, namely batteries **B1**, **B2**, **B3** and **B4** in FIG. **22A**. The motor **36** thus runs at only a preselected fraction of its full speed and the pump unit **100** outputs irrigation liquid pulses at a desired frequency and amplitude, which are less than the maximum available. The apparatus is thus operated in its low output mode. The colliding of the free end of the trigger arm **251** with the contact leaf **267** gives tactile feedback to the user, that the low output mode of the handpiece has been selected.

Further pulling in of the trigger lever **242** by the user causes the beveled free end of the arm **251** to bend rightwardly (FIG. **4A**) the contact leaf **267** to a dotted line position indicated at **267C**, allowing the free end of the arm **251** to override the contact leaf **267**, such that the contact blade **253** moves into its "full-pull" dotted line position **253C** and further bends the motor contact **270** its dotted line position **270C**. In this final position, the contact blade **253** establishes electrical contact between the motor contact **270** and

the contact leaf **267**, thereby applying the full series voltage of all eight of the batteries **B1–B8** to the motor **36** to operate the latter at its full speed and thereby drive the pump unit **100** at its full output, namely to provide irrigation liquid pulses out of the pump unit **100** at maximum pulse amplitude and frequency.

When the user releases the trigger lever **242**, the resiliently bent trigger lever **242**, due to its inherent resilience, springs back from its fully pulled-in position indicated in broken lines at **242P**, to its solid line rest position indicated at **242** (FIG. **4A**). The electrical connection between the contact **262** or **263** and the contact **270** is broken.

Suction Hose

A flexible suction hose **280** (FIGS. **2** and **3**) is led along within the housing (within the lower part of the housing in FIG. **3**) past the drive unit **25** and pump unit **100**. The above-mentioned clamp plate **165** includes a tubular structure molded thereinto and defined by a forward nipple **282** in the handle **12** and, in coaxial fluid communicating relation therewith, a rearward nipple **283** which extends rearwardly out of the bottom end **164** of the handpiece handle **12**. The rear end portion **281** of the suction hose **280** is sealingly and fixedly telescoped over the front nipple **282**. A conventional flexible hose, not shown, is conventionally and sealing telescopable over the rear nipple **283** for connecting same to a conventional suction source, as schematically indicated at SS in FIG. **3**.

The front end portion **284** of the suction nose **280** is sealingly telescoped over a rearward opening nipple **285** on a short suction conduit **286** (FIGS. **2**, **3**, **16**, **17**

and 18). The suction conduit **286** (FIG. 18) is fixed side by side, in piggyback fashion, on the periphery of the irrigation liquid conduit **143** and hence is a part of (preferably an integral plastic molded part of) the bellows housing **104**.

The clamp plate **165** serves several purposes. It provides a suction hose connection, bears on the irrigation liquid hose where it enters the handpiece housing, and helps align the rear (rightward in FIG. 4) end wall portions of the housing halves as they are assembled together, and in so doing, is itself fixed on the housing. In addition, the clamp plate **165** is of one piece, preferably a plastic molding, and is partially recessed into the handpiece so that it does not make the handpiece look any bigger.

Tip Unit

A tip unit **291** (FIGS. 8, 8A and 8B) is releasably fixable on the front end of the handpiece **10** and extends forward therefrom for applying irrigation liquid pulses and/or suction to a surgical site indicated schematically at SU in FIGS. 8 and 8B. The tip unit **291** (FIG. 8) comprises a coupling **292**, a front cover **293** fixed to the front of the coupling **292**, and an elongate hollow wand **294** extending forwardly from the coupling and front cover for aiming at a surgical site SU. The coupling **292**, cover **293** and wand **294** are preferably one piece molded plastic units. The wand **294** is preferably of clear plastics material.

The tip unit **291**, and more specifically the coupling **292**, is releasably fitted in fluid tight relation to the front of the bellows housing **104** of the pump unit **100** and is releasably latched within the open front end of

the handpiece housing barrel 13 as hereinafter discussed.

More particularly, the coupling 292 (FIG. 8) comprises a shallow, forward opening cup 295 having a flat base wall 296 from which forwardly extends a shallow peripheral wall 297, thereby defining a forward opening recess 300. Coaxial irrigation liquid nipples 301 and 302 extend fixing rearwardly and forwardly, respectively, from the base wall 296 and together define a coaxial bore 303 therethrough and through the base wall 296. The rear nipple 301 is snugly but slidably receivable rearwardly into the open front portion of the liquid outlet conduit 143 of the bellows housing 104. An O-ring 304 seats in an annular groove outward facing on the rear nipple 301 and sealingly engages the interior of the liquid outlet conduit 143 to prevent irrigation liquid leakage therebetween.

The wand 294 includes a coaxial, relatively small diameter, irrigation liquid outlet tube 305 which at its rear end is telescoped fixedly and sealingly within the bore 303 of the front and rear nipples 301 and 302 for receiving a pulsed flow of irrigation liquid from the irrigation liquid outlet conduit 143 of the bellows housing 104.

The coupling 292 further includes a suction nipple 306 fixedly extending rearward from the base wall 296 in spaced parallel relation with the irrigation liquid nipple 301. The suction nipple 306 is snugly insertable rearwardly coaxially into the front opening suction conduit 286 of the bellows housing 104. An O-ring 310 is axially sandwiched between the rear end of the suction nipple 306 and a front facing annular step 311 at

the rear end of the suction conduit 286 to prevent leakage therebetween.

The coupling 292 further includes a leaf spring-like, generally U-shaped latch arm 312 which extends rearward from the peripheral portion of the base wall 296, curves radially outwardly and forwardly, and extends forward past the front cover 293, in radially outwardly spaced relation from the wand 294. A wedge-shaped, transverse ridge 313 on the exterior base of the latch arm 312 is approximately centered between the front and rear ends of the latch arm. A circumferentially extending, radially inward protruding rib 314 (FIGS. 2, 3 and 8) on the interior face and at the open front end of the right housing part 15 (at the front end of the barrel 13) opposes the latch arm 312, immediately ahead of the ridge 313, with the tip unit 291 installed on the front end of the handpiece 10 as shown in FIG. 8. The ridge 313 has a front facing step which abuts interferingly with the housing rib 314 to releasably block removal of the tip unit from its installed condition shown in FIG. 8. To remove the tip unit from the front end of the handpiece, the user simply presses radially inward against the forward protruding end portion 315 of the springy latch arm 312, sufficient to radially inward displace the ridge 313 out of interfering relation with the rib 314 and thereby unlatch the tip unit from the front end of the handpiece. This allows forward removing the tip unit 291 from the open front end of the handpiece barrel 13 and removing of the irrigation liquid and suction nipples 301 and 306 from the liquid outlet conduit 143 and suction conduit 286 of the bellows housing 104.

The tip unit 291, or any alternative tip unit having a substantially identical coupling and front cover, can

be installed operatively on the front end of the handpiece **10** by inserting same into the open front end of the handpiece barrel **13** so that the nipples **301** and **306** enter the liquid and suction conduits **143** and **286** respectively, to their position shown in FIG. 8. During this installation, the forward facing slope of the wedge cross-section transverse ridge **313** slides rearwardly past the housing rib **314**, bending the springy latch arm **312** radially inward as generally indicated by the arrow L in FIG. 8, so that the wedge cross-section ridge **313** can snap rearwardly past the rib **314** at the open front end of the housing barrel **13**. Thus, the tip unit **314** can be slid axially into the front end of the barrel **13** and upon reaching its innermost position latches itself against unintended removal. In its installed condition of FIG. 8, the tip unit is substantially rigidly fixed with respect to the front end of the bellows housing **104** and hence with respect to the handpiece barrel **13**.

The front cover **293** (FIG. 8) comprises a plate **320** which extends radially of the wand **294** and of the length axes of the barrel **13** and the pump unit **100**. The peripheral shape of the plate **320** conforms to the cross-sectional shape of the front end of the barrel **13**, so that the perimeter of the plate **320** is substantially flush with the outer periphery of the open front end of the barrel **13**, and so that the plate **320** effectively covers the open front end of the barrel **13**. The peripheral shape of the plate **320** and cross-sectional shape of the front end of the barrel **13** in one embodiment is generally D-shaped, with a generally flat underside and a convexly curved top and sides. The plate **320** is not intended to seal the open front end of the barrel **13** and so need not tightly abut same. Since the peripheral wall **297** of the cup **295** fits easily within the

open front end of the barrel 13, the plate 320 extends radially outwardly beyond the cup 295, as seen in FIGS. 8, 8A and 8B.

The front cover 293 includes an annular flange 322 extending axially rearwardly therefrom, radially snugly into the cup 295 of the coupling 292 to bottom rearwardly and sealingly against a resilient gasket 321 which is disposed against the front face of the base wall 296 of the cup 295. Respective holes in the gasket 321 loosely surround the front nipple 302 and leave fully open the communication between the interior of the suction nipple 306 and the interior of the cup 295. The front cover 293 further includes a further annular flange 323 extending fixedly and forwardly from the plate 320 in coaxial alignment with the through hole 324 in the plate 320.

The rearward annular flange 322 of the front cover 293 is fixedly secured within the cup 295 of the coupling 292 by any convenient means, for example by snap fit connectors on the opposing faces of such flange 322 and the peripheral wall 297 of the cup 295. For example, the cup peripheral wall 297 may be provided with several circumferentially spaced rectangular holes 325 (FIGS. 8A and 8B) for snap fit reception therein of small radially outward extending protrusions schematically indicated at 326 on the outside of the rearward annular flange 322.

The wand 294 further includes a relatively large diameter elongate suction tube 330 (FIGS. 8A and 8B) which loosely coaxially surrounds the irrigation liquid outlet tube 305 (FIG. 8) and extends substantially to the front end of the latter. The rear end portion 331 of the suction tube 330 is radially enlarged to provide a

radially shallow, axially elongate flange protruding radially outward therefrom and which is axially trapped between the plate **320** and the gasket **321** backed by the base wall **296**. This serves to rigidly fix the suction tube **330** with respect to the coupling **292** and front cover **293**. A port **332** in the sidewall of the suction tube **330** near its rear end communicates with a loosely surrounding annular chamber **333** defined between the plate **320** and base wall **296** of the front cover **293** and coupling **292** respectively.

The front end of the irrigation liquid tube **305** is held coaxially fixed within the front end portion of the surrounding suction tube **330** by any convenient means, such as radial, circumferentially spaced, webs **334** (FIG. 8). Accordingly, with a tip unit **291**, of the general type above described, installed on the front end of the handpiece, as shown in FIG. 8, irrigation liquid pulses from the pump **100** pass forwardly within the liquid tube **305** and are projected from the front (left in FIG. 8) end thereof, as schematically indicated by the arrows PL. At the same time, liquid and particulate debris at the surgical site SU are drawn into the front (left in FIG. 8) end of the suction tube **330**, pass rearwardly along the length thereof, through the port **332** into the chamber **333** and rearwardly through the nipple **306** and suction nipple **285**.

With the exception of a few components such as the motor **44**, the various electrically conductive contacts, the elongate insulated conductors, the various seal rings (for example **105**, **154**, **304** and **310**, the gasket **321**, as well as the suction and irrigation liquid hoses, the remaining major components, while possibly manufacturable of a variety of materials, are economically manufacturable of available molded plastics materials.

For example, the valve member 131 may be of rubber or a synthetic substitute or similar resilient plastic. Similarly, the bellows 101 is preferably molded of a suitable resilient plastic material capable of the bellows expansion and contraction movements shown in the drawings. The trigger unit 240 and the latch arm 312, while of substantially rigid plastics material, are elastically bendable to the extent required to suit the present description. Similarly, components to be snap-fitted together are substantially rigid but have sufficient resilience to permit the required described snap fitting.

The present invention can be constructed at relatively low cost and is thus practically manufacturable as a disposable tool, both the handpiece 10 itself and the accompanying electric power supply unit 190 being disposable after use with a single surgery patient.

OPERATION

The apparatus is quickly and easily assembled. The drive unit 25 (FIG. 12) is assembled by, in effect, "dropping in" elements in proper sequence into the right (lower in FIG. 12) shell 31 and covering same with the other shell 30. More particularly, output gear 60, face gear 54 and motor 36 (with attached pinion gear 53 and electric contacts 270 and 271) are "dropped" into their respective locations in the upturned shell part 31, in that sequence. The rectangular shaft 61, topped by the eccentric member 62, drops into the corresponding hole in the output gear 60 and the link member 51 drops onto the eccentric member. The other shell part 30 is then snap fitted over the filled shell part 31, completing the drive unit 25.

The pump unit **100** is assembled by coaxially telescoping together its elements shown in FIG. **18** and then plugging into the inlet port **146** (FIG. **19**) the elbow **151** with the O-ring **154** and hose **160** assembled thereon.

The stub **120** (FIG. **18**) of the drive unit **100** can then be snapped into the slot **122** of the drive unit fork **71** (FIG. **2**) to connect the drive unit **25** operatively to the pump unit **100**. The suction hose **280** can then be connected to the pump unit nipple **285** and to the nipple **282** on the clamp plate **165**. Thereafter, the two assemblies above described can be laid into the rightward (FIG. **2**) housing part **15** in the following order, namely liquid hose **160** (FIG. **4**), drive unit **25** and pump unit **100** (FIG. **3**) and, last, suction hose **280** and clamp plate **165**.

The trigger unit **240** is then placed, with its rightward (FIG. **2**) pivot stub **243** located in the corresponding boss **244** in the rightward housing part **15**, and its arm **251** inserted through the hole **252** (FIG. **4A**) into the interior of the handle portion of the rightward housing part **15**, as seen in FIGS. **4** and **4A**. The trigger arm **251** is "covered" by the rear portion **281** of the suction hose **280** in FIG. **3**. The electrical contacts **262** and **263** are placed on their respective posts **255** and **256** in the rear portion of the rightward housing part **15** and the three forward electrical connectors **175** are secured respectively to the mentioned contacts **262** and **263** and the motor contact **271** (FIG. **4A**). Thereafter, the leftward (FIG. **2**) housing part **14** can be snap fitted to the rightward housing part **15** to close same and enclose the above mentioned apparatus, shown in FIG. **3**, therein.

In the thus assembled handpiece, the drive unit is fixedly located by engagement of its drive axis bosses **84** and **85** (FIG. **5**) in corresponding bosses in the housing parts **14** and **15** (see for example at **96** in housing part **15** in FIG. **2**). Location of the drive unit **25** is assisted by the ribs **95** within the housing parts **14** and **15** and by snug resilient engagement of the drive unit **25** by the hoses **160** and **280** which flank it.

The drive unit shell **26** is configured to maintain the proper tolerances between meshing gears and related parts. Location of all the drive unit parts in the drive unit shell **26** reduces the need to maintain close tolerances in the larger and less specialized handle housing **11**. Even the housing tolerances, for locating the pump unit **100** with respect to the drive unit **25** in the housing **11**, need not be close since the bellows **101** are flexible enough to bend or otherwise distort to absorb minor mis-alignment or angulation of the reciprocation axis of the link member **51** with respect to the length axis of the pump unit **100**. Indeed, the ribs **95** in the housing **11** permit pivoting of the drive unit **25** about the axis of the bosses **96** to allow the drive unit **25** and pump unit **100** to settle into their own working relative orientation. Accordingly, the precision in the handpiece housing **11** can be concentrated in aspects of fitting together of the two housing halves.

The electric power supply unit **190** (FIG. **22**) is quickly and easily assembled. More particularly, the feet of the respective battery contacts **210**, **211**, **212** (FIGS. **26–28**) are slid downward into their respective grooves (FIGS. **23A** and **23B**) in the pan **192** (FIG. **22**) with their protruding toes resiliently gripping the sides of the grooves. The rear connectors **176** are con-

nected to the battery contact fingers 224 and 225 in the order shown in FIG. 22A. The batteries B1–B8 are then slipped down into the pan in the orientation shown in FIG. 22 and into electrically conductive engagement with the battery contacts 210, 211 and 212 indicated in FIG. 22A. The rear portion of the liquid hose 160 is laid atop the batteries as indicated in FIG. 23, with the square flange 182 nonrotatable in the boss 235, and the cover 193 is snap fitted atop the liquid hose 160 and battery filled pan 192, as shown in FIG. 23, to complete assembly of the power supply unit. The cap 185 is pressed onto the sharpened tip 184 to protect it prior to use.

The result is a disposable pulsed irrigation handpiece unit which is entirely self-contained, including its own power supply, and which is ready for use upon having its sharpened tip 184 plugged into a conventional irrigation liquid supply bag or the like, and a conventional manner.

It should be noted that virtually the entire handpiece 10 and power supply unit 190 can be assembled without need for any adhesives, the parts going together with friction or snap fits or, in the case of the joinder of the bellows housing 104 to the bellows 100 and elbow 151, by being held together by surrounding structure which in turn is snap fitted together. This greatly eases and speeds assembly. A minor exception is that the fitting 180 is here adhesively fixed to the hose 160.

To use the handpiece assembly in surgery, the cap 185 (FIG. 23) is removed from the pointed tip 183, which is then plugged into a standard output fitting on a conventional irrigation liquid supply bag. The

power supply unit **190**, being fixed to the rear end of the irrigation liquid hose **160**, can be allowed to simply hang from the irrigation liquid supply bag (not shown but schematically indicated at S in FIG. **22**). By providing a substantial length of irrigation liquid hose **160** (for example 10 feet), the liquid supply bag S and power supply unit **190** can be located well out of the way of the surgical team during use of the handpiece **10** at the surgical site. Even then, the power supply unit **190** is compact as compared to the adjacent conventional irrigational liquid supply bag (being very little larger than the eight conventional double AA batteries that it houses).

If suction will be desired at the surgical site, the handpiece nipple **283** (FIG. 3) can be connected by a conventional hose not shown to a conventional suction source SS (FIG. 3).

A variety of tip units **291** of differing characteristics (e.g. differing irrigation liquid spray patterns, etc.) may be made available for alternative mounting on the handpiece **10**. One example is shown in FIGS. 8, 8A and 8B.

In any event, the user selects a tip unit **291** having a wand **294** of desired configuration, and rearwardly inserts its coupling **292** into the front end of the handpiece **11**. More particularly, the nipples **301** and **306** of the tip unit are inserted coaxially rearwardly, in sealed relation (see FIG. 8) in the conduits **143** and **286** respectively of the bellows housing **104**. The resilient latch arm **312** enters the barrel **13** of the handpiece housing **11** adjacent to the bellows housing **104** until the plate **320** of the front cover **293** abuts the front end of the handpiece housing barrel **13**. In the

last part of this tip installation movement, the wedge shaped ridge **313** (FIG. 8) on the latch arm **312** snaps past the rib **314** of the housing barrel **13** to positively prevent forward removal of the tip unit from the handpiece.

To use the apparatus for irrigation of a surgical site, the user grips the handpiece, either by the handle **12**, in a pistol-like manner, or where the barrel **13** joins the handle **12**, in a wand like manner. In either position, the user has one or more fingers that can bear on and press inwardly the trigger lever **242** from its inoperative rest position shown in solid line in FIG. **4A** forward and through its low speed and high speed positions indicated in broken lines at **253B** and **253C** in FIG. **4A**. In the first operative position **253B**, the blade **253** connects the low speed (here six-volt) contact **266** to the motor contact **270**. On the other hand, in the fully depressed condition of the trigger, indicated at **253C**, the blade **253** connects the high speed, 12 volt contact **267** with the motor contact **270**. Accordingly, the user can select between "off", lower power pulsing and high power pulsing.

In one embodiment pump stroke was about ¼". In one embodiment shown, the motor speed was about 15,000 rpm and the speed reduction afforded by the transmission was about 15-1, providing the eccentric with about 1,000 rpm speed.

Depending on the flow resistance of the particular tip unit attached to the handpiece, the liquid pulse frequency may change. In one example, a handpiece according to the invention produced about 1200 pulses per minute, dispensing about 1600 ml per minute of irrigation liquid in about 1.3 ml liquid pulses. The pos-

itive drive of the pump unit by the drive unit and the location of the pump unit, near the front end of the barrel **13** and in direct engagement with the tip unit, provides liquid pulses at the output of the tip unit which have sharp rise and fall slopes. Thus, the relationship of liquid pulse amplitude to time approximates a square wave form, more so than for example, the aforementioned device of U.S. Pat. No. 5,046,486. Further, the force applied to the pulses by the present apparatus is higher (somewhat above one Newton) than in that prior art device, at the full power position of the trigger.

In one embodiment according to the invention, a tab **316** (FIGS. **1** and **8B**) extends forward from the front plate **320** of the front cover **293**, on the opposite side of the wand **294** from the latch arm **312**. To release the latch arm **312** from the housing **11**, the user can thus simply simultaneously grip with opposite fingers and pinch toward each other the latch arm **312** and tab **316**. In other words the tab **316** provides base toward which to pinch, or pull, the latch arm **312** to release the tip unit **291** from the handpiece **11**.

In the present invention, the liquid and suction nipples of the tip unit connect directly to the pump unit **100**, and do not contact any part of the handpiece housing **11**. Accordingly, neither the pump unit **100** nor tip unit **291** need fit with close tolerances the handpiece housing **11**. The connection of the tip unit to the handpiece housing is merely to latch the tip unit against loss from the handpiece housing and to casually cover the open front end of the handpiece housing. Accordingly, the liquid tight fit is between the nipples of the tip unit and conduits of the pump unit, not with the housing.

Although a particular preferred embodiment of the invention has been disclosed in detail for illustrative purposes, it will be recognized that variations or modifications of the disclosed apparatus, including the rearrangement of parts, lie within the scope of the present invention.

The invention claimed is:

1. A medical irrigator comprising:

a housing shaped to be hand held and having a front end;

an inlet tube extending to said housing;

a pulse pump capable of operating at a variable rate disposed in said housing and having an outlet conduit that opens to the housing front end, said pump configured to receive fluid from said inlet tube and discharging the fluid through said outlet conduit;

a single electric motor disposed in said housing and connected to said pump for actuating said pump, said motor operable at variable speeds to control the pumping rate of said pump;

a control assembly disposed in said housing to regulate the speed of said motor;

a suction tube disposed in said housing that has an open end adjacent the front end of said housing that extends away from the front end;

a battery pack separate from said housing; and

a flexible conductor assembly extending from said battery pack to said housing for supplying energy stored in said battery pack to said motor.

2. The medical irrigator of claim 1, wherein said control assembly has a switch that is moveably mounted to said housing, said control assembly configured so that:

when said switch is in a first position, said control assembly does not supply an energization signal to said motor;

when said switch is in a second position, said control assembly supplies a first energization signal from said battery pack to said motor; and

when said switch is in a third position, said control assembly supplies a second energization signal from said battery pack to said motor.

3. The medical irrigator of claim 2, wherein said switch is pivotally attached to said housing.

4. The medical irrigator of claim 3, wherein said switch is configured to move:

from the first position and to the second position; and

from the second position to the third position.

5. The medical irrigator of claim 2, wherein said switch is configured to move:

from the first position and to the second position; and

from the second position to the third position.

6. The medical irrigator of claim 1, wherein said pump is bellows pump.

7. The medical irrigator of claim 1, wherein said housing is formed to have: a handle; and a barrel integral with and located above said handle that extends forward from said handle, said barrel having the housing front end from which said pump discharges fluid and from which said suction tube extends.

8. The medical irrigator of claim 1, wherein said pump is a reciprocating pump.

9. The medical irrigator of claim 1, wherein said inlet tube extends from said battery pack to said housing.

10. A medical irrigator having:

a housing shaped to be hand held, said housing having a front face shaped to receive a medical/surgical tip assembly;

a discharge conduit disposed in said housing that opens into the front face of said housing and a suction tube that extends from the housing front face, both said discharge conduit and said suction tube being configured to be connected to separate conduits integral with the tip assembly;

an inlet line connected to said housing;

a pump disposed in said housing connected to receive fluid from said inlet line and pump fluid

out through said discharge conduit, said pump being a pulse pump that operates at a variable rate;

a single, variable speed electric motor in said housing that is connected to said pump that actuates said pump so as to regulate the pumping rate of said pump;

a conductor assembly including a plurality of flexible conductors, said conductor assembly having a distal end disposed in said housing and a proximal end spaced from said housing;

a battery pack separate from said housing, said battery pack attached to said conductors at the proximal end of said conductor assembly; and

a switch assembly mounted to said housing for selectively establishing a connection between at least one of said conductors and said motor, said switch assembly having a switch element moveably attached to said handle, said switch assembly being configured so that:

when said switch element is in a first position, said switch assembly does not supply an energization signal to said motor;

when said switch element is in a second position, said switch assembly supplies a first energization signal from said battery pack to said motor; and

when said switch element is in a third position, said switch assembly supplies a second energization signal from said battery pack to said motor.

11. The medical irrigator of claim 10, wherein said switch element is pivotally attached to said housing.

12. The medical irrigator of claim 10, wherein said switch element is configured to move:

from the first position and to the second position; and

from the second position to the third position.

13. The medical irrigator of claim 10, wherein:

said conductor assembly includes: a first conductor over which a first energization signal from said battery pack is supplied; and a second conductor over which a second energization signal from said battery pack is supplied; and

said switch assembly is configured so that:

when said switch element is in the second position, said switch assembly connects said first conductor to said motor; and

when said switch element is in the third position, said switch assembly connects said second conductor to said motor.

14. The medical irrigator of claim 10, wherein said switch assembly includes a single conductive member that is directly connected to said motor.

15. The medical irrigator of claim 10, wherein said pump is a bellows pump.

16. The medical irrigator of claim 10, wherein said switch element is pivotally attached to said housing.

17. The medical irrigator of claim 10, wherein said pump is a reciprocating pump.

18. The medical irrigator of claim 10, wherein said inlet tube extends from said battery pack to said housing.

19. The medical irrigator of claim 10, wherein:

said inlet line is a flexible hose that extends from outside said housing into said housing; and

said conductor assembly is attached to said hose so that at least a portion of said conductor assembly extends along said hose.

20. A medical irrigator comprising:

a housing shaped to have a front end;

a suction tube disposed in said housing having an inlet end that opens from the front end of said housing;

a pulse discharge pump that operates at a variable rate disposed in said housing having an inlet and discharge conduit, the discharge conduit opening towards the front end of said housing;

an inlet line that extends into said housing that is in fluid communication with the pump inlet;

a single electric motor disposed in said housing and connected to said pump to actuate said pump,

said motor operating at variable speeds to regulate the pumping rate of said pump;

a battery pack separate and spaced from said housing that contains at least one battery that stores energy for energizing said motor;

a flexible cable that extends from said battery pack to said housing for supplying energy from said battery pack to said motor; and

a control assembly integral with said housing, said control assembly having a switch member moveably mounted to said housing and said control assembly being configured to apply a variable energization signal from said battery pack to said motor so as to control the speed of said motor and regulate the pumping rate of said pump.

21. The medical irrigator of claim 20, wherein said control assembly is configured so that said switch member moves sequentially from a first position to a second position and from the second position to a third position and:

when said switch member is in the first position, the switch member does not establish a connection between said cable and said motor;

when said switch member is in the second position, the switch member establishes a connection between said cable and said motor to cause a first energization signal to be applied to said motor; and

when said switch member is in the third position, the switch member establishes a connection be-

tween said cable and said motor to cause a second energization signal to be applied to said motor.

22. The medical irrigator of claim 20, wherein:

said cable includes a first conductor over which a first energization signal is available from said battery pack and a second conductor over which a second energization signal is available from said battery pack; and

said control assembly is configured so that switch member can be selectively positioned to: connect neither of said cable conductors to said motor; connect the first said cable conductor to said motor; or connect the second said cable conductor to said motor.

23. The medical irrigator of claim 22, wherein said control assembly is configured to sequentially move from the position in which neither said cable conductors are connected to said motor to the position in which said first cable conductor is connected to said motor and to the position in which the second said cable conductor is connected to said motor.

24. The medical irrigator of claim 20, wherein said pump is a reciprocating pump.

25. The medical irrigator of claim 20, wherein said pump is a bellows pump.

26. The medical irrigator of claim 20, wherein said inlet line extends from said battery pack to said housing.

27. The medical irrigator of claim 20, wherein:

said inlet line is a flexible hose that extends from outside said housing into said housing; and

said cable is attached to said hose so that at least a portion of said cable extends along said hose.

28. A medical irrigator, said irrigator comprising:

a housing having a front face shaped to receive a medical tip assembly;

a pulse discharge pump that operates a variable rate, said pump having an inlet and an outlet, the outlet opening into the front face of said housing so as to be in fluid communication with a first conduit of the tip assembly;

a suction tube in said housing having an open end located adjacent the front face of said barrel so as to be in fluid communication with a second conduit of the tip assembly;

a single, variable speed electrical motor disposed in said housing connected to said pump for actuating said pump at variable rates;

a battery unit separate from said housing for supplying energy to said motor;

a control assembly mounted to said housing and connected to said battery unit and to said motor for supplying a variable potential energization signal to said motor, said control assembly having a single switch member that is moveably attached to said housing that selectively

makes/breaks a connection between said battery unit and said motor and establishes the potential of the energization signal supplied to said motor.

29. The medical irrigator of claim 28, wherein said control assembly is configured so that said switch member moves sequentially from a first position to a second position and from the second position to a third position and:

when said switch member is in the first position, the switch member does not establish a connection between said battery unit and said motor;

when said switch member is in the second position, the switch member establishes a connection between said battery unit and said motor to cause a first energization signal to be applied to said motor; and

when said switch member is in the third position, the switch member establishes a connection between said battery unit and said motor to cause a second energization signal to be applied to said motor.

30. The medical irrigator of claim 28, wherein said control assembly has a first contact over which a first energization signal is available from said battery unit and a second contact over which a second energization signal is available from said battery unit and said control assembly is configured so that said switch member can be selectively positioned to: connect neither of said contacts to said motor; connect the first said con-

tact to said motor; or connect the second said contact to said motor.

31. The medical irrigator of claim 30, wherein said control assembly contacts are statically mounted to said housing.

32. The medical irrigator of claim 30, wherein said control assembly is configured so that said switch member moves sequentially from:

a position in which no energization signal-supply contacts are connected to said motor to a position in which said first contact is connected to said motor; and

from the position in which said first contact is connected to said motor to a position in which said second contact is connected to said motor.

33. The medical irrigator of claim 28, wherein said pump is a reciprocating pump.

34. The medical irrigator of claim 28, wherein said pump is a bellows pump.

35. The medical irrigator of claim 28, wherein a flexible cable extends from said battery unit to said control assembly.

36. The medical irrigator of claim 28, wherein said housing includes a handle and a barrel that extends above and projects forward of said handle, said barrel having the front face of said housing.

37. The medical irrigator of claim 28, wherein:

a flexible hose extends from outside said housing into said housing through which fluid is supplied to the pump inlet; and

a flexible cable extends from said battery unit to said housing, said cable being connected to said control assembly and being attached to said hose so that at least a portion of said cable extends along said hose.

38. A medical irrigator, said irrigator comprising:

a housing having a front face shaped to receive a medical tip assembly;

a pulse discharge pump disposed in said housing that operates at a variable rate, said pump having an inlet and an outlet, the outlet opening into the front face of said housing so as to be in fluid communication with a first conduit of the tip assembly;

a suction tube in said housing having an open end located adjacent the front face of said housing so as to be in fluid communication with a second conduit of the tip assembly;

a single, variable speed electric motor disposed in said housing connected to said pump for actuating said pump at variable rates;

a battery pack separate from said housing containing at least one battery;

a flexible cable that extends from said battery pack to said housing, said flexible cable having at least one conductor over which an energization

signal from said at least one battery is supplied; and

a control assembly attached to said housing and connected between said at least one conductor and said motor for supplying a variable potential energization signal to said motor, said control assembly having a single switch member that is moveably attached to said housing that selectively makes/breaks a connection between said at least one conductor and said motor and that establishes the potential of the energization signal supplied to said motor.

39. The medical irrigator of claim 38, wherein said control assembly is configured so that said switch member moves sequentially from a first position to a second position and from the second position to a third position and:

when said switch member is in the first position, the switch member does not establish a connection between said at least one conductor and said motor;

when said switch member is in the second position, the switch member establishes a connection between said at least one conductor and said motor to cause a first energization signal to be applied to said motor; and

when said switch member is in the third position, the switch member establishes a connection between said at least one conductor and said motor to cause a second energization signal to be applied to said motor.

40. The medical irrigator of claim 38, wherein:

said cable has a first conductor over which a first energization signal is available from said at least one battery and a second conductor over which a second energization signal is available from said at least one battery; and

said control assembly is configured so that switch member can be selectively positioned to: connect neither of said cable conductors to said motor; connect the first said cable conductor to said motor; or connect the second said cable conductor to said motor.

41. The medical irrigator of claim 40, wherein said control assembly has a first contact to which said first cable conductor is attached and a second contact to which said second cable conductor is attached and said contacts are statically mounted to said housing.

42. The medical irrigator of claim 40, wherein said control assembly is configured so that said switch element moves sequentially from:

a position in which no energization signal-supplying conductors are connected to said motor to a position in which said first cable conductor is connected to said motor; and

from the position in which said first cable conductor is connected to said motor to a position in which said second cable conductor is connected to said motor.

43. The medical irrigator of claim 38, wherein an inlet hose extends from said battery pack to said

housing, said inlet hose being connected to the pump inlet.

44. The medical irrigator of claim 38, wherein said housing is shaped to have a handle and a barrel integral with said handle that is located above and projects forward of said handle.

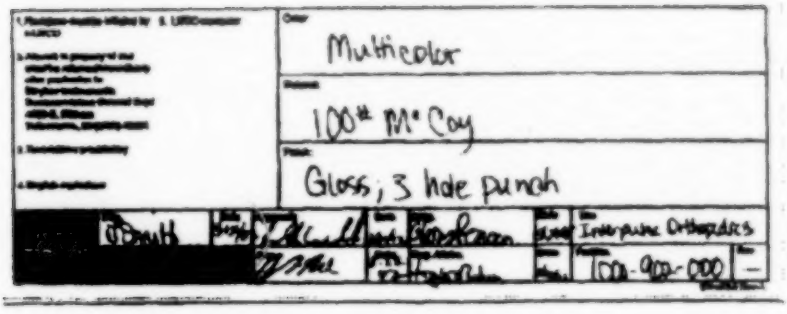
45. The medical irrigator of claim 44, wherein said motor is disposed in said housing handle.

46. The medical irrigator of claim 38, wherein:

a flexible hose extends from outside said housing into said housing through which fluid is supplied to the pump inlet; and

said cable is attached to said hose so that at least a portion of said cable assembly extends along said hose.

* * * * *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Complete Ordering Information

InterPulse Battery Powered Irrigation

InterPulse Handpiece

Part #	Description
210-100	Handpiece (Handpiece with suction)
210-110	Handpiece (Handpiece with suction with Bone Cleaning Tip
210-115-100	Handpiece (Handpiece with suction with Cranial Bone Cleaning Tip
210-112	Handpiece (Handpiece with suction with Soft Tissue Tip
210-113	Handpiece (Handpiece with suction with High Flow Tip
210-114-100	Handpiece (Handpiece with suction with Cranial High Flow Tip
210-116	Handpiece (Handpiece with suction with Pin Spray Tip
210-116-100	Handpiece (Handpiece with suction with Cranial Pin Spray Tip
210-148	Handpiece Handpiece with Dual Suction Adapter
210-149	Handpiece Handpiece with High Flow Tip with Dual Suction Adapter
210-147	Handpiece (Handpiece with suction with High Flow Tip with Dual Suction Adapter
210-207	Adapter only Handpiece Handpiece
210-230	Adapter only Handpiece Handpiece with Bone Cleaning Tip
210-117	Adapter only Handpiece Handpiece with Soft Tissue Tip
210-114	Adapter only Handpiece Handpiece with High Flow Tip
210-116	Adapter only Handpiece Handpiece with Pin Spray Tip

Tips and Accessories

Part #	Description
210-1	Round Tip with Collar
210-5	Round Tip
210-7	Fluted Tip
210-8	Fluted Tip
210-9	Fluted Tip
210-10	Bone Cleaning Tip
210-10-100	Cranial Bone Cleaning Tip
210-12	Soft Tissue Tip
210-13	High Flow Tip
210-14-100	Cranial High Flow Tip
210-16	Irrigation Only Tip
210-17	Pin Tip
210-16	Pin Spray Tip (pack)
210-16-100	Cranial Pin Spray Tip
210-34	Modular Soft Tissue Suction Shield
210-37	Soft Tissue Tip and Accessories (Suction Tubing)
210-38	Pin Spray Tip and Replacement Suction Tubing
210-20	Interpulse Rechargeable Power Pack
211-24	Interpulse Battery Charger
210-100	Interpulse Rechargeable Hand Piece

InterPulse Handpiece, Rechargeable

Part #	Description
211-100	Interpulse Rechargeable Handpiece
211-110	Interpulse Rechargeable Handpiece with Bone Cleaning Tip
211-112	Interpulse Rechargeable Handpiece with Soft Tissue Tip
211-113	Interpulse Rechargeable Handpiece with High Flow Tip
211-116	Interpulse Rechargeable Handpiece with Pin Spray Tip
211-200	Interpulse Rechargeable Irrigation Only Handpiece
211-215	Interpulse Rechargeable Irrigation Only Handpiece with Bone Cleaning Tip
211-212	Interpulse Rechargeable Irrigation Only Handpiece with Soft Tissue Tip
211-214	Interpulse Rechargeable Irrigation Only Handpiece with High Flow Tip
211-216	Interpulse Rechargeable Irrigation Only Handpiece with Pin Spray Tip

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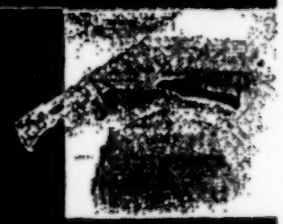

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PulsaJet®

Battery Powered Irrigation System

March 11, 1998

Zimmer Inc.
Business Case / Proforma

Project name: *PulsaJet*® Battery Powered Irrigation System
Prepared By: Carol Duvall, Product Manager; Tim Donaldson, Project Manager
Revision: 5
Date: March 11, 1998

Executive Summary:

Project Scope / Overview

Business Rationale

(A Major Program Should Be Described In 6 to 8 Paragraphs Which Outline A Brief History, The Current Situation And Recommended Future Action. It should Describe The Product and Associated Instruments, Provide An Overview Of Impact On Existing Products And A Macro View Of The Estimated Schedule. It Should Address; Is it An Extension Within an Existing Segment? Does It Involve A Developing Market? Why It's Required? It Should Describe Strategy And Basis Of All Assumptions Made in Developing Plan And Explain How It Will Fit Overall Corporate Strategic Objectives And What Are Probable Scenarios If We Don't Do This Project Or If Project Execution Varies From Plan?

Zimmer Patient Care Division has been one of the leaders in the pulsatile lavage market since the release of the *Pulsavac*® Wound Debridement System in the mid 1980's. We have placed nearly 5,000 machines into this market. This market not only enjoys

lucrative hospital operating room business for total joint surgery, but other areas such as wound care, physical therapy, trauma (both in the emergency room and operating room), and even general surgery. We were able to establish ourselves as a leader because of the abilities of the *Pulsavac* System. These key features included: consistent performance, variable pressure, concurrent/concentric suction and irrigation, and a wide variety of debridement tips.

However, the market, especially the operating room market, has moved from more of a product performance sell to a convenience sell. There are a variety of factors influencing this shift in customer preference, such as limited space in the operating room and user convenience. The ability to quickly set-up a battery unit out weighed the high performance of a machine within certain hospitals.

Stryker, Inc. was the first company to capitalize on this with their disposable battery system, the Surgi-Lav-Plus. This product was able to take operating room business away from us over the past three years. Davol, Inc. now offers two battery units, the Simpulse Solo and Var-I-Care Systems. These battery powered systems, with their quick set-up and lack of capital equipment requirements have made a major impact on the market. They offer improved user convenience without providing the performance capabilities of our *Pulsavac* System.

To counter this attack, we are recommending the development of a product that offers the convenience of the various battery powered systems on the market with improved performance, reliability, and ergonomics. This new unit will allow us to gain a competitive

market share and assist us in meeting Patient Care's strategic goal of increasing sales in Wound Debridement. This new device will take the place of our current *Var-A-Pulse* unit which has meager market position in the operating room due to poor performance and product quality issues.

Zimmer Inc.
Business Case/Proforma

Project name: *PulsaJet*® Battery Powered Irrigation System
Prepared By: Carol Duvall, Product Manager; Tim Donaldson, Project Manager
Revision: 5
Date: March 11, 1998

- **The Current Product – *Var-A-Pulse***

Zimmer Patient Care Division attempted to compete in the disposable battery system market with the release of the *Var-A-Pulse* in March 1996. This is a product which was rushed to the market and has been dogged by reliability and functionality issues since its release. It is a poorly designed product with little thought given to ergonomics or user needs.

Since its release, many design changes directed at increasing reliability have been implemented. These changes appear to have been beneficial as complaints on reliability issues have been significantly reduced. Nevertheless, there are other concerns which remain. Specifically, these are: 1)poor flow rate, 2)ergonomically deficient, and 3)tips fall off during procedures.

Flow Rate: Attempts at improving the flow rate of the current design have been somewhat unsuccessful in lab testing. All relevant components have been optimized for this application. The *Var-A-Pulse* employs a very inefficient design for a battery powered pumping mechanism due to the high friction between mating and moving components. It is Product Development's belief that this mechanism cannot deliver the required performance characteristics with the current essential design constraints.

Ergonomics: It is doubtful that significant improvements in the ergonomics of the *Var-A-Pulse* can be achieved unless a complete redesign of the pumping mechanism is undertaken. This is because the internal placement of the vital components dictated the shape of the handgun. Ergonomics will be a key focal point of the *PulsaJet* because we feel this is an area where we can gain notable superiority over the competitive units. Even as clumsy and uncomfortable as the *Var-A-Pulse* is, some still consider it to have a better "feel" than either Stryker's or Davol's unit. When we design the *PulsaJet* system with the user needs as a vital characteristic, we may be able to make sales based on the ergonomic aspect alone.

Tip Attachment: Tips falling off of the gun has been a minor problem for ZPCD for years. There are "ears" attached to the handgun which are meant to introduce a more mechanical interference between the gun and tips. This method is inadequate, especially at the tolerance extremes. Moreover, the problem is amplified with the *Var-A-Pulse* because it does not have the ears to provide even minimal support. The addition of a true locking mechanism for tips is a crucial design input for the *PulsaJet*. The strategy is that af-

ter the design of the new locking mechanism is validated, it would be introduced across the *Pulsavac* line. To get a jump on the validation process, Product Development would like to propose the introduction of widespread use of the design, prior to the release of the *PulsaJet*, by integrating it on the *Var-A-Pulse* as soon as the design is complete. This would not only serve to improve the *Var-A-Pulse* in the interim, but will provide feedback on the design so we ensure that we "do it right the first time" on the *PulsaJet*.

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Executive Summary:

Assessing the costs required in resources, time, and dollars to complete an adequate redesign of the current product, it is seemingly not justified versus a design of a completely new system. It will cost only modestly more to introduce a new design that Zimmer can be proud of instead of one that we would like to put behind us.

- **The Proposed Product**

General Description:

The *PulsaJet* will be a dual speed, battery operated pulsatile wound irrigation/debridement device which will offer simultaneous aspiration. The device will be packaged with various tips for different applications. These tips will feature a unique attachment method to the *PulsaJet* unit which will ensure that they do not fall off during surgical procedures. The *PulsaJet* will be designed with performance, reliability, ergonomics, and cost in mind. These are the four areas which are most lacking in the current *Var-A-Pulse* device. The goal of this project is to design a device which will meet or beat the current competition in flow rate and perceived pressure at a lower cost than the current Var-A-Pulse unit and works properly every time it is used.

Marketing Requirements:

1. Single use, Disposable
2. Powered by batteries
3. Requires no capital equipment for use
4. Handgun design with pull-on activation
5. Must be able to lock in the "on" position during operation
6. Tips should attach to handgun with mechanical means
7. Pre-attached suction/irrigation tubing (12-15 ft long)
8. Two settings: High – Flow rate of 1200 ml/min, Low – approximately half of High setting
9. Pulsatile fluid delivery, 10 Hz minimum
10. Must be self priming
11. CE marked
12. Component kit target cost of $16.00; packaged and sterilized.

An additional input to be considered is the possibility of designing a tip which will allow this product to be used in physical therapy. This would be a high flow, low pressure tip that would allow for the treatment of chronic wounds. Total costs (including tooling) to add this tip would be approximately $15,000.

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Revision: 5
Date: March 11, 1998

Executive Summary:

- **The Strategy**

This product will be a nationwide release. Our primary target will be orthopaedics, Specifically total hip and knee procedures. The target audience will be current users of competitive systems such as Stryker's SurgiLav-Plus and Davol's Simpulse and Simpulse Solo Systems.

- **The Market**

The primary market focus for the *Pulsavac* System remains the orthopaedic surgeon involved with cementing a prosthesis, normally a knee or hip implant. The *Pulsavac* System serves to clean cancellous bone prior to cementing the prosthesis into place. The cleaning of the bone allows for a stronger bone to im-

plant bonding effect, which in turn facilitates a stronger implant fixation. This segment will continue to supply the *Pulsavac* System with its major users.

However, there are secondary market applications of the *Pulsavac* System, which include the ER/Trauma market, wound care market, and general O.R. procedures.

- **The Resources**

Required resources for this project are summarized in Appendix A of this document.

- **The Schedule**

The current project plan (Gantt Chart) indicates a launch date of May 1, 1999. This is the date that we can expect inventory quantities to be available to support continuous and uninterrupted sales. The Gantt Chart is attached to this document (Appendix B); however, some key milestones are summarized below.

4/6/98 - Officially Begin Development (Assumed Project Approved)
9/16/98 - Design of All Components Complete
1/6/99 - Tooling Complete
1/20/99 - Preproduction Pilot Run Begins
3/4/99 - Field Evaluations Begin
4/19/99 - Production Begins
6/1/99 - Product Launch Date

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Revision: 5
Date: March 11, 1998

Executive Summary:

- **The Risks**

In not developing this product we risk the loss of additional market share to competitors such as Stryker and Davol. We would be able to maintain share in our capital segment with those users who prefer the higher impact pressures associated with the capital equipment, however, with our focus on hips, knees, and trauma in the operating room, we have turned away from a lucrative market in nursing home chains. This will also have a negative impact on our capital equipment sales. The development of an improved battery system will allow us the opportunity to increase our share within the operating room through the use of a totally disposable system.

This past January, Stryker released what they are claiming to be an improved version of their battery powered unit. To this point, word that we are receiving from the field indicates that no major innovations have been made to the product; however, the color has changed and the tip attachment has improved. Just the fact that they have made improvements indicates that they are not standing still with their product line.

- **The Business Impact**

Sales projections have been provided (page 12) based on maintaining our current battery-powered

product, the *Var-A-Pulse*, with no changes made to the design. We would have difficulty maintaining sales and our capital sales will decrease based on market moves towards disposable products. Moderate changes to the current design (lock on for tips, trigger change) would not be significant enough to allow us a strong market position in the disposable market.

Projections with a new design (increase flow, ergonomic handpiece) will allow us to capture market share and propel us to a strong leadership position in the disposable market.

Capital market projections include only those disposables that are used in conjunction with a capital piece of equipment. The disposable market projections are battery operated systems and accessories used with those systems.

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Executive Summary:

- **The Assumptions**

(List The Assumptions Used For Each Element Of The Plan, (as applicable), As They Relate To The Various Scenarios Described In The Plan)

- Market Direction / Opportunity Size
  - Competition remains the same
  - Release is June 1, 1999
  - Global trends were based on U.S. growth statistics
  - The need for irrigation will continue
- Proposed Product Design / Feature Competitiveness
  - Stryker flow rate = 1200 ml/min (claim) with showerhead tip
  - Stryker pressure = 6.8 psi (claim) with showerhead tip
  - Tip locking mechanism within scope of project
  - New tip design will be required
- Pricing Position
  - Battery units are discounted heavily
  - Current average selling price was used as our base for future sales
- Resources Required / Capacities
  - Var-A-Pulse will be discontinued after Pulsajet introduction
  - Forecast is accurate
- Project Schedule
  - Project is approved on or before April 6, 1998
  - All requested resources are appropriated
  - Product is manufactured in Dover
  - 510(k) is not required

- Regulatory Approval Path

    - Safety and effectiveness will not change significantly
    - No new marketing claims will be documented
    - Performance characteristics within realm of current products

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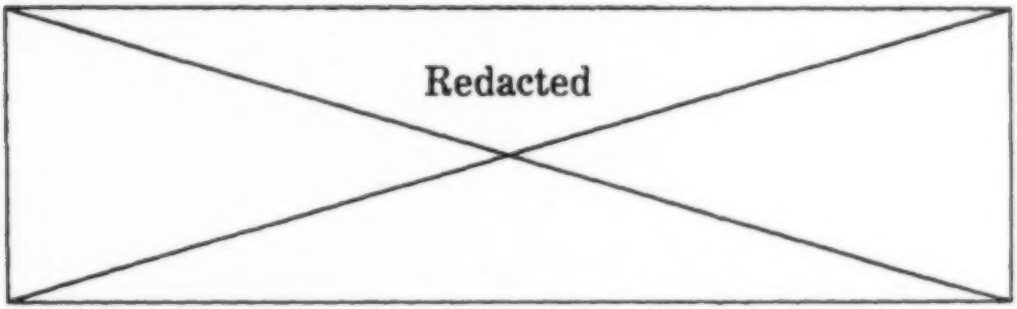
Executive Summary:

Regulatory Path:

A 510(k) will not be required for this product. There are no additional safety or effectiveness issues nor will there be a change in intended use or Marketing claims. The product will be CE marked. This is not expected to impact project schedule.



The Numbers:

	Year 1	Year 2	Year 3	Year 4	Year 5
Incremental Sales:	$3.9M	$6.5M	$8.6M	$10.9M	$13.5M
Return on Sales:	32.3%	20.6%	22.6%	23.2%	23.7%
Promotion:	$244K	$85K	$60K	$60K	$60K

Cash Flow: **$5.9M** (after discounting 12%)

Investment: $259K to $421K – Development Expenses
$300K to $475K – Capital Tooling

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Marketing Input:

Market Size / Growth / Market Opportunity

(On A Major Program This Section Will Require 2-3 Pages Which Describe Current Market With Historical And Future Growth Trends. Define Market Drivers, Current And Future Customer Profiles And Buying Trends. Supplemental Graphics To Illustrate Market Are Recommended.)

The market for debridement products is currently at $40 million domestically based on IMS data. The market is predominantly held by three key players:

Zimmer – $13 million or 35% market share
Stryker – $15 million or 41% market share
Davol – $9 million or 24% market share

The rate of growth in the hospital operating room market is low, approximately 1-2% per year. Growth will be driven primarily through competitive conversions with the development of this product. However, additional growth opportunity exists in the physical therapy market in the treatment of chronic wounds.

This market could potentially contribute $3-5 million in the short-term.

Threats to current business may exist in the cannibalization of current *Pulsavac* business in the operating room. Also, the physical therapy market creates challenges in the area of reimbursement for disposables used in lavage/debridement procedures.

Timing for the release of this project is urgent. Stryker, Inc. and Davol have aggressively marketed their battery system which has allowed them to gain market share over the past two years. Zimmer's market share with our current battery system has eroded due to poor performance and product quality issues.

The problems we are facing with our current design is not only forcing us out of the disposable market, but may also eliminate us from being a player in the lavage market in the future. By analyzing the lavage market by segmenting it between capital equipment and disposable products, we can see a definite decline in the market for capital equipment.

By using these same trends and projecting over the next five years, we can see a definite trend toward the use of disposable products. (Graphs attached – Appendix C)

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Marketing Input:

Competitive Analysis

(Each Key Competitor In This Product Area Should Be Assessed. A Product Feature / Utility And Comparison Of Strengths And Weaknesses Should Be Provided. Describe Current Competitive Market Shares And Trends. What Is The Anticipated Competitive Response To This Program And Associated Risks? Charts and graphs with narrative explanation preferred)

Stryker Corporation: Located in Kalamazoo, Michigan. Product development efforts have been intense in terms of introducing new pumps and disposable debridement systems. Their introduction of the Surgi-Lav system, the first battery operated system on the market, helped propel their growth in the operating room. This was followed by the Surgi-Lav Plus, a system operated by nitrogen, to allow them to compete effectively against Davol.

Stryker has not done much in terms of their capital piece of equipment, the Orthotec Pump. However, there are machines remaining in the field. Stryker had been updating capital equipment by replacing old units with new ones at no cost to the account.

Stryker Strengths

–Strong presence throughout the orthopaedic market in terms of their overall product line and corporate history.
–Market innovators.
–Full line of debridement tips.
–Strong positioning in the O.R. segment, especially orthopaedics.
–Aggressive targeting of large accounts.

Stryker Weaknesses

–Quality problems with earlier systems.
–Easy to swap-out Stryker capital machines.
–Only spikes one solution bag.
–Lacks an effective splash-free tip.

Davol Corporation: Located in Cranston, Rhode Island. The product is distributed through Davol's network of field sales representatives and occasionally through regional medical supply houses. Davol was the next to introduce a battery operated system into the market, the Simpulse Solo. They followed this with a product targeted toward the wound care market, the Var-I-Care System, also battery operated.

Prior to their battery system, the most notable feature of their systems were that they were nitrogen driven. They were able to achieve impressive growth and market share given they were not the initial market innovators. Davol's unit share decreased in the early 90's which led to their introduction of the battery system.

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Marketing Input:

One of Davol's primary sales tactics has been to approach Zimmer accounts with low pricing. Also, they stress their product features such as "no capital equipment", easy set-up, and a cone-shaped tip which resembles the Zimmer cone-shaped tips. Another aspect of Davol's price competition in that they often "bundle" their products with other Davol products in contracts offering significant discounts.

Davol Strengths

- –No capital purchase required.
- –Bundling contracts with wound drainage products.
- –Aggressive salesforce.
- –Full line of debridement systems.
- –Increased account targeting (wound care market)

Davol Weaknesses

- –Awkward handpiece.
- –Strongest presence is in the nitrogen driven market.

–Tips are not effective in reducing splash-back.
–Suction tubing is not included with product.

Pricing Analysis

(Provide Detailed Pricing Strategy, Segmentation Strategy (i.e., managed care). Describe Competitive Position Comparison And Anticipated Response To Pricing Strategy. Address Price / Volume Implications. (Charts and graphs with narrative explanation preferred.)

The chart below provides the average selling price for wound debridement disposables as based on H.S.I. data. Included are two categories, capital equipment and disposables.

	1994	1995	1996	1997
Capital Equipment				
Zimmer	$15.63	$15.92	$19.75	$17.96
% Growth		1.82%	19.39%	-9.97%
Stryker	$18.47	$19.83	$21.21	$20.18
% Growth		6.86%	6.51%	-5.10%
Duval	N/A	N/A	N/A	N/A
% Growth				
Disposables				
Zimmer	N/A	N/A	$37.77	$35.07
% Growth				-7.70%
Stryker	$26.08	$27.26	$26.27	$24.83
% Growth		4.33%	-3.77%	-5.80%
Duval	$21.18	$22.78	$34.35	$27.11
% Growth		7.02%	33.68%	-26.71%

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Marketing Input:

Existing Product Impact/SKU's

(Describe The Plans For Phase Out Of Existing Products And Current Customer Transition As Required By Introduction Of New Product)

The current *Var-A-Pulse* system will be obsoleted once the PulsaJet is introduced.

Product Description

General Description:

The *PulsaJet* will be a dual speed, battery operated pulsatile wound irrigation/debridement device which will offer simultaneous aspiration. The device will be packaged with various tips for different applications. These tips will feature a unique attachment method to the *PulsaJet* unit which will ensure that they do not fall off during surgical procedures. The *PulsaJet* will be designed with performance, reliability, ergonomics, and cost in mind. These are the four areas which are most lacking in the current *Var-A-Pulse* device. The goal of this project is to design a device which will meet or beat the current competition in flow rate and perceived pressure at a lower cost than the current *Var-A-Pulse* unit and works properly every time it is used.

Disposable Kit Components

PulsaJet Unit
Modified *Shower Tip*

Modified *Fan Spray Tip*
Modified *Intramed. Tip*

Cases Required

There will be no cases required for this product.

Packaging And Labeling

The standard packaging configuration for the current product is tray packing. This would be an acceptable method for the *PulsaJet*; however, we will be investigating the possibility of Tyvek pouch packaging due to the potential cost savings.

Marketing Launch Plan:

(Describe how it will be executed. Is it a Roll Out? A Simultaneous Release? By Country, Region, Or Specific Surgeons? Charts And Graphs May Be Used To Illustrate The Impact Of Various Scenario Choices In Product Introduction. 2-3 pages preferred.)

Sales Collaterals

The *PulsaJet* System is scheduled for release June 1, 1999. The sales force information packet will include a salesforce announcement, price/commission sheet, 2-sided sell sheet, inservice video, impact pressure sheet, and product profiler.

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Marketing Input:

Promotions

Samples - Each Distributor will receive an allotment of 5 samples for the first 5 months of the product release. Orders for these samples must be made through a Zimmer Patient Care Division Marketing Assistant in Warsaw, IN. Samples over and above this amount can be purchased at a Distributor discount of list less 70%.

Try-It-Pricing - Competitive accounts evaluating the *PulsaJet* will be offered 50% off list pricing for up to two boxes of product. We will pay (E) commission on all conversion orders.

Top 100 Zimmer Hip and Knee Accounts - New debridement business (accounts not purchasing *Pulsavac System* products within the previous 12 months) will deliver (E) commission. This can be a *Pulsavac II* or *PulsaJet* conversion.

Product Release Advertising/Education Requirements:

These costs are summarized on page 18

Product Release Inventory Requirements:

No. Of Sets	Dollar Value	Time Required
600 (sale units)	96000	7 weeks

Sales Forecast

		Year 1	Year 2	Year 3	Year 4	Year 5
New Product						
PulsaJet	Units	173,800	300,379	378,173	467,263	566,587
	Dollars	$ 5,214,000	$ 7,773,809	$ 9,824,935	$12,130,147	$14,725,440
	A.S.P.	$ 30.00	$ 25.88	$ 25.98	$ 25.96	$ 25.99
Existing Product						
Pulsevac	Units	843,301	783,903	728,211	675,170	627,732
	Dollars	$12,700,617	$12,509,328	$12,322,298	$12,137,523	$11,955,001
	A.S.P.	$ 15.06	$ 15.96	$ 16.92	$ 17.97	$ 19.04
* *Var-A-Pulse*	Units	36,800	36,800	35,800	35,800	34,800
	Dollars	$ 1,290,576	$ 1,290,576	$ 1,255,506	$ 1,255,506	$ 1,220,436
	A.S.P.	$ 35.07	$ 35.07	$ 35.07	$ 35.07	$ 35.07
Incremental						
PulsaJet	Units	137,000	263,579	342,373	431,463	531,781
	Dollars	$ 3,923,424	$ 6,483,233	$ 8,569,429	$10,874,641	$13,505,004

* The hypothetical forecast for Var-A-Pulse is supplied for reference only. This product will be discontinued upon release of the Pulsajet.

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Development Engineering Input:

Project Team Members

- Project Manager - Tim Donaldson
- Marketing Product Manager - Carol Duvall
- Manufacturing Engineer(s) - Chris Finn (Dover)
- Packaging Engineering/Labeling - Brad Durcholz
- Purchasing - Steve Winkler (Dover)

- Regulatory – Paula Osorio (Dover)
- Clinical – TBD if necessary
- Inventory Planning – Jeff Hootman (Dover)

Skill Sets Required, Headcount, and Commitment Level

(Summarize requirements form attached Resource Requirement Timeline)

See Attached Chart (Appendix A) for Commitment Level and Duration

Development Program Expense Budget:

See Attached Chart (Appendix A) for Development Expense Budget

Research Laboratory Expenses

Research laboratory expense is not anticipated for this project.

Project Schedule:

(Describe and Summarize the key milestones of the program and attach Gantt chart. Schedule Should Reflect Realistic And Achievable Timing Using Input From Marketing, Development, Manufacturing and Distribution. Explain Critical Path Activities And Potential Risks To Schedule. Describe Impact Of Delays And Contingency Plans As Required.)

The Gantt Chart is attached to this document in Appendix B.

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Manufacturing Input:

Manufacturing Build Plan:

	Year 1	Year 2	Year 3	Year 4	Year 5
New Product					
Pulsajet	173800	300379	378173	467263	566587
Existing Product					
Pulsavac	843301	783903	728211	675170	627732
Vac-A-Pulse	0	0	0	0	0

Make Versus Buy Analysis

(Describe Options To Source And Associated Costs / Logistics)

We intend to look at practical possibilities in the manufacture of the product, both internally and externally. It is likely that the Dover facility would provide the best quality product at a competitive cost.

Facilities/Tooling/Equipment; Capital Investments

(Describe Cost And Timing Of Investment And Obsolescence On Existing Equipment. Will Equipment Be Leased, Purchased, Or Rented?)

If the product is produced in Dover, no new equipment or facilities will be required. Note: These

figures do not include any equipment that would be required by an outside manufacturer.

Head Count Additions/Deletions:

(Describe Production And Manufacturing Human Resource Requirements.)

Since the current *Var-A-Pulse* will be obsoleted once the *PulsaJet* is introduced, the capacity would initially be available in Dover to produce the *PulsaJet* without headcount or facility addition. However, if the forecast as accurate, the large volume jump in the second year on would necessitate the addition of personnel. For reference, Dover is currently running 1 shift. A typical shift can produce approximately 1200 units per week. This equates to 62,400 per year (assuming 8 hours shifts, 5 person crews). If we look at the volume in the second year, 4.8 shifts per week will be required to keep up with demand. This definitely indicates that additional manufacturing personnel will be required within the first year.

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Manufacturing Input:

Capabilities and Resources:

(Do We Have The Personnel, Management Systems, Direct Or Related Previous Production Experience With This Type Of Production Process? Do We Have The Capabilities To Meet The Projected Release Date? If Not, Why?)

The manufacturing processes of this product are very similar to many items that Dover currently manufactures. We have direct production experience with all aspects of the proposed design. If we keep the manufacture internal, we definitely have the capabilities to meet or beat the projected launch date.

Manufacturing Process Assessment

(Identify The Issues And Requirements Related To Existing Equipment And Capacity Available. Are New Processing Methods Required To Meet Design/Performance/Cost Requirements?)

This product is essentially a disposable plastic tubing set. This is Dover's greatest area of expertise. No new processing methods are expected - the assembly will be very similar to the current product. If the decision is made to take the manufacturing outside of Zimmer, it is not possible at this time to identify equipment or process requirements until we determine that manufacturer's capabilities.

Packaging Resources:

(Identify Specific Requirements For This Project Related To People Required, Equipment, And Necessary Changes To Packaging Materials Over Existing Materials Required.)

One of the cost savings ideas that we definitely want to evaluate is Tyvek pouching the product versus using the tray packs which are currently used. This potentially could add up to a $1.20 per unit cost savings. The pouches are currently being made in Dover and evaluating this possibility would require minimal resource and expense. Either way we go, pouches or trays, a packaging validation would be required.

Outsourcing Requirements:

(Identify All Resources That Are Expected To Be Outsourced, i.e.; Instruments, Machining, Casting, Etc..)

Product Management's input on this project was that the standard cost target should be $18.50 (for reference, the current standard cost of the *Var-A-Pulse* is $18.67). In looking at the best and worst case scenarios, in terms of development costs, it would cost between $394K and 630K to meet the above input in the established time frame. Development's plan is to focus on a standard cost of $16.00. I estimate that it will cost an additional $143K to 226K in tooling and resources. However, at the additional $2.50/unit savings, this would equate to **$4.7M** added to the bottom line over the first five years. A potential disadvantage is that it may result in a 1 to 3 month delay in product launch date. Outsourcing potentially could be required to hit a lower target.

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Manufacturing Input:

Materials/Sourcing Plan

(Are The Required Materials Current Or New? How Will New Materials Be Integrated Into Stock Planning Cycles?)

It is anticipated that a new material will be used in this product. This material will have fluid path contact, so it will need to undergo Cytotoxicity, Sensitization, and Intracutaneous Toxicity testing. All other materials are anticipated to be current and approved.

Standard Cost Estimates

High

	Year 1	Year 2	Year 3	Year 4	Year 5
New Products					
Pulmo Jet	16.00	17.10	17.61	18.14	18.69
Existing Products					
Pur-A-Pulse	19.25	19.83	20.42	21.04	21.67
Incremental					
	-1.25	-2.73	-2.81	-2.90	-2.98

Medium

	Year 1	Year 2	Year 3	Year 4	Year 5
New Products					
Pulmo Jet	16.00	16.00	16.32	16.65	16.97
Existing Products					
Pur-A-Pulse	18.89	19.06	19.45	19.83	20.23
Incremental					
	-2.89	-3.06	-3.13	-3.18	-3.26

Low

	Year 1	Year 2	Year 3	Year 4	Year 5
New Products					
Pulmo Jet	15.00	15.00	15.15	15.30	15.45
Existing Products					
Pur-A-Pulse	18.00	18.18	18.36	18.55	18.73
Incremental					
	-3.00	-3.18	-3.21	-3.25	-3.28

[redacted]

Orthopedic Implant Division

PulseJet Battery System

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Units		-	-	-	-	-
Existing		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
New		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Incremental		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Sales						
Existing		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
New		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Incremental		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cost of Goods Sold						
Incremental		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cost of Goods Sold	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Gross Profit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Program Expense Budget						
Travel	[redacted]	[redacted]				
Engineering	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Clinical and other R&D Costs	[redacted]	[redacted]	-	-	-	-
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Royalties		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Commissions		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Promotional						
Advertising		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Promotion		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Training		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Other (Specify)		[redacted]	-	-	-	-
Total Advertising and Promotion		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total Costs	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Net Revenue	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total Cash Flows After Discounting at 15%	[redacted]					
Revenue Split		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Capital Requirements						
Tooling	[redacted]					

[redacted]

[redacted]

Return on Investment and Payback Calculation
($ 000's Omitted)

GROUP/DIVISION	LOCATION	DATE	RETURN ON INVESTMENT
Orthopaedic Insight		10-Mar-98	187.23%
PROJECT TITLE			PAYBACK PERIOD
Pursuit Battery System			8.7 YEARS

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
					Net Income or Savings								
Calendar Year	Time Period	Total Investment	Dir. Earnings Before Depr., COM, & Inc. Taxes	Depreciation	Before Depr. & I.T. [Col. 4-5]	After Depr. & I.T. [Col. 6 x 52%]	Reinv. & Recovery of Assets	Total Cash Return [Col. 6+7+8]	Net Cash Flow [Col. 6-3]	Discount Factor @ 187.23%	Discount Cash Flow Column [Col. 10x11]	Discount Factor @	Discount Cash Flow Column [Col. 10x13]
	-3				-								
	-2												
	-1												
1997	[illegible]	[illegible]	-	-	-	-		-	[illegible]	1.0000	[illegible]	1.0000	
1998	1	80.8	1,022.8	88.7	988.3	817.6		794.3	893.6	0.3488	264.08		
2000	2		1,344.8	91.9	1,252.7	795.3		887.3	887.3	0.1811	120.83		
2001	3		1,626.6	44.3	1,581.6	1,105.7		1,210.0	1,210.0	0.0949	71.39		
2002	4		2,508.4	31.8	2,476.6	1,926.6		1,957.3	1,957.3	0.0239	38.73		
2003	5		3,184.3	28.3	3,156.0	1,894.2		1,888.5	1,888.5	0.0099	17.73		
2004	6		-	28.3	(28.3)	(16.3)		10.0	10.0	0.0039	0.04		
2005	7		-	28.3	(28.3)	(16.3)		10.0	10.0	0.0013	0.01		
2006	8		-		-	-		-	-	0.0005	-		
2007	9		-		-	-		-	-	0.0002	-		
2008	10		-		-	-		-	-	0.0001	-		
N/A	Total	9658.1	$10,856.2	$303.3	$8,752.8	$6,046.8	-	$6,869.1	$6,791.0	N/A	-	N/A	-

Zimmer
Orthopedic Implant Division
PulseJet Battery System

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Units						
Existing						
New						
Incremental						
Sales						
Existing						
New						
Incremental						
Cost of Goods Sold						
Incremental						
Cost of Goods Sold						
Gross Profit						
Program Expense Budget						
Travel						
Engineering						
Clinical and other R&D Costs						
Supplies						
Commissions						
Promotion						
Advertising						
Promotion						
Training						
Other (Demand)						
Total Advertising and Promotion						
Yield Gain						
Net Revenue						
Yield Gain Flows After Discounting at 15%						
Return on Sales						
Capital Requirements						
Tooling						

Return on Investment and Payback Calculation
($ 000's Omitted)

GROUP/DIVISION Orthopaedic Implant	LOCATION	DATE 10-Mar-98	RETURN ON INVESTMENT 113.00%
PROJECT TITLE Pulsejet Battery System			PAYBACK PERIOD 0.9 YEARS

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
Calendar Year	Time Frame	Total Investment	Dir. Earnings Before Depr., COM, & Inc. Taxes	Depreciation	Net Income or Savings Before Depr. & I.T. (Col. 4-5)	Net Income or Savings After Depr. & I.T. (Col. 6 x 62%)	Reinv. & Recovery of Assets	Total Cash Return (Col. 5+7+8)	Net Cash Flow (Col. 6-3)	Discount Factor @ 113.00%	Discount Cash Flow Column (Col. 10x11)	Discount Factor @	Discount Cash Flow Column (Col. 10x13)
	-3												
	-2												
	-1												
1996	Ref. Pt.	$798.6	-	-	-	-		-	($798.6)	1.0000	($798.60)	1.0000	
1998	1	138.7	1,342.7	137.8	1,104.8	685.0		822.8	684.2	0.4695	324.89		
2000	2		1,344.8	98.8	1,246.1	772.6		871.1	871.1	0.2204	191.99		
2001	3		1,828.0	78.3	1,859.7	1,152.6		1,230.9	1,230.9	0.1035	128.36		
2002	4		2,568.4	68.2	2,468.2	1,524.1		1,574.3	1,574.3	0.0486	76.51		
2003	5		3,184.3	41.8	3,152.4	1,954.5		1,996.4	1,996.4	0.0228	45.52		
2004	6		-	41.8	(41.8)	(26.0)		15.8	15.8	0.0107	0.17		
2005	7		-	41.8	(41.8)	(26.0)		15.8	15.8	0.0050	0.08		
2006	8		-	-	-	-		-	-	0.0024	-		
2007	9		-	-	-	-		-	-	0.0011	-		
2008	10		-	-	-	-		-	-	0.0005	-		
N/A	Total	$936.3	$10,316.0	$482.8	$9,733.4	$6,034.7	-	$6,517.3	$5,581.0	N/A	$0.01	N/A	-

Zimmer Inc.
Business Case / Proforma

Project name: *PulsaJet*® Battery Powered Irrigation System
Prepared By: Carol Duvall, Product Manager; Tim Donaldson, Project Manager
Revision: 5
Date: March 11, 1998

OpCom Approvals **Date _____**

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Zimmer Inc.

Business Case / Proforma

PulsaJet® Battery Powered Irrigation System

Appendix A

Development Cost Summary

PulseJet
$16.00 Target Cost
Estimated "Best Case" DEVELOPMENT COSTS

DESCRIPTION	1998 J	F	M	A	M	J	J	A	S	O	N	D	TOTAL 1998	1999 J	F	M	A	M	J	J	A	S	O	N	D	TOTAL 1999	TOTAL $16.00 Target
Program Manager - DB	0.3	0.3	0.5	0.8	0.8	0.8	0.7	0.6	0.5	0.6	0.8	1.0	7.7	0.8	0.3	0.3	0.2	0.2	0.1							1.9	9.6
Manufacturing Engineer - DB	0.0	0.0	0.2	0.2	0.2	0.2	0.3	0.4	0.6	0.6	0.8	0.8	4.6	0.4	0.3	0.2	0.1	0.1								1.1	5.1
Drafting	0.0	0.0	0.5	0.8	0.8	0.4	0.5	0.3	0.2	0.3	0.3	0.2	4.3	0.2	0.1	0.1										0.4	4.7
Technician	0.0	0.0	0.5	0.8	0.8	0.5	0.8	0.5	0.8	0.7	0.8	1.0	7.2	1.0	0.5	0.3	0.1									1.9	9.1
	(used $ 6,500/mo or cost)											Sub-Total	$160,800												Sub-Total	$40,200	$191,000
Testing Costs													$300,000														300,000.0
Fixture Costs (bits)													$3,500														3,500.0
Testing Costs (Toxicity / Biocompatibility)													$5,000													$1,000	6,000.0
Prototype Costs (Field Eval. / Validation)													$40,000														40,000.0
Travel Costs													$8,000													$9,500	$17,500
Outside Design													$1,000														1,000.0
												Sub-Total	$357,500												Sub-Total	$10,500	$368,000
TOTAL COSTS													**$518,300**													**$50,700**	**$559,000**
Note: No cost estimate for support groups																											

PulseJet

$16.00 Target Cost

Estimated "Worst Case" DEVELOPMENT COSTS

DESCRIPTION	1998 J	F	M	A	M	J	J	A	S	O	N	D	TOTAL 1998	1999 J	F	M	A	M	J	J	A	S	O	N	D	TOTAL 1999	TOTAL $16.00
Program Manager - D6	0.0	0.0	1.0	1.0	1.0	1.0	0.8	0.8	0.8	0.8	0.8	1.0	8.0	1.0	1.0	1.0	0.8	0.6	0.4	0.2	0.1	0.1				5.2	14.1
Manufacturing Engineer - D5	0.0	0.0	0.5	0.8	0.5	0.8	0.8	0.5	0.8	0.7	0.8	1.0	8.3	1.0	0.8	1.0	0.8	0.3	0.5	0.2	0.1					4.3	10.5
Drafting	0.0	0.0	1.0	1.0	1.0	1.0	0.8	0.3	0.3	0.3	0.3	0.5	6.8	1.0	0.4	0.3	0.1									1.8	8.3
Technician	0.0	0.0	1.0	1.0	1.0	1.0	0.8	0.5	0.8	0.8	1.0	1.0	8.9	1.0	1.0	0.5	0.2	0.2	0.1							3.0	11.8
	(used $ 8,500/mo fix rate)											Sub-Total	$188,678												Sub-Total	$108,880	$307,285
Testing Costs													$475,000														475,000.0
Fixture Costs (Mfg)													$7,500														7,500.0
Testing Costs (Toxicity / Biocompatibility)													$12,500														12,500.0
Prototype Costs (Field Eval. / Validation)													$45,000													$7,000	52,000.0
Travel Costs													$12,000													$15,000	$27,000
Outside Design													$15,000														15,000.0
												Sub-Total	$567,000												Sub-Total	$22,000	$589,000
TOTAL COSTS													**$755,678**													**$130,880**	**$896,285**
Note: No cost estimate for support groups																											

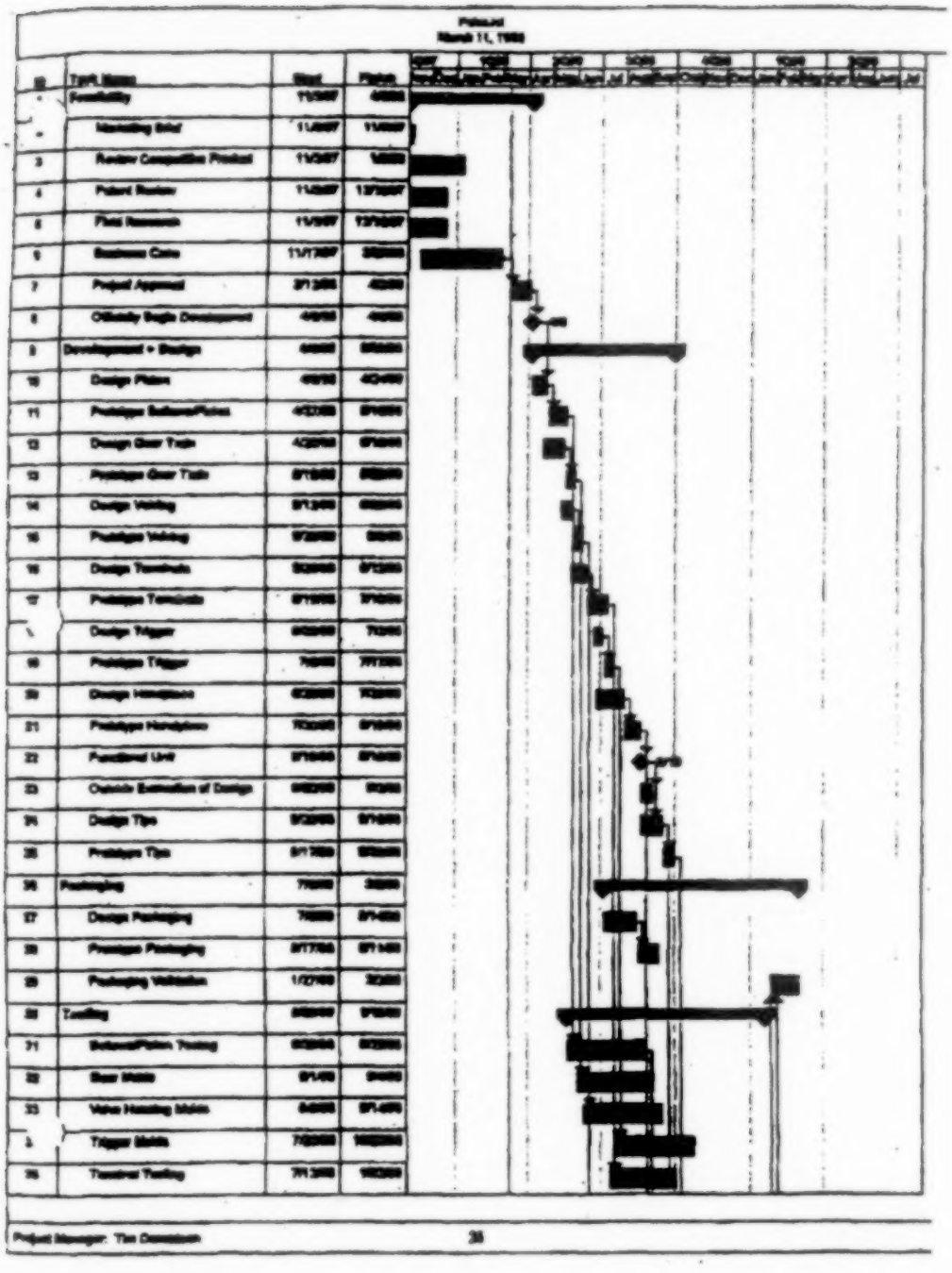
Zimmer Inc.

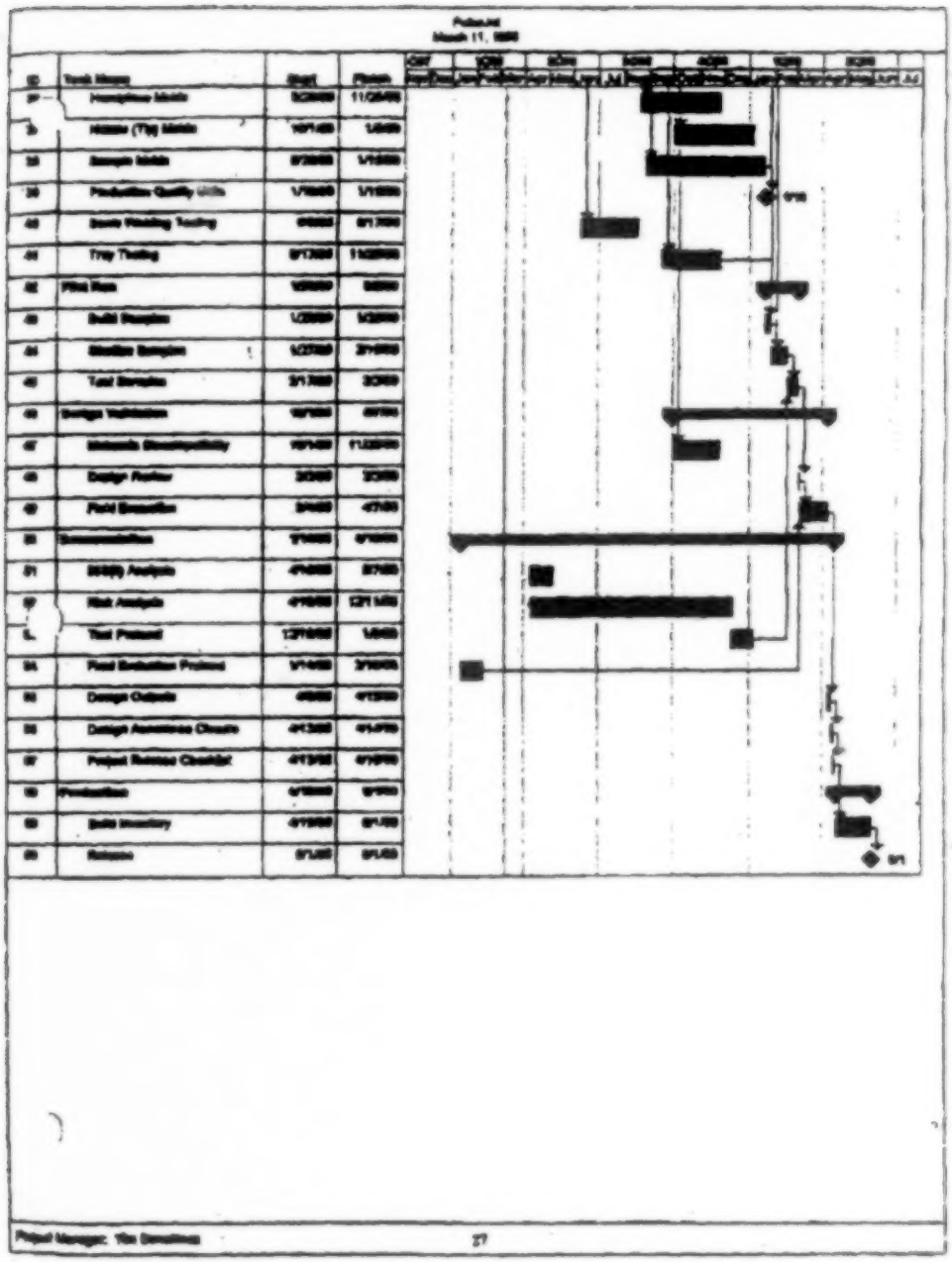
Business Case / Proforma

PulsaJet® Battery Powered Irrigation System

Appendix B

Gantt Chart





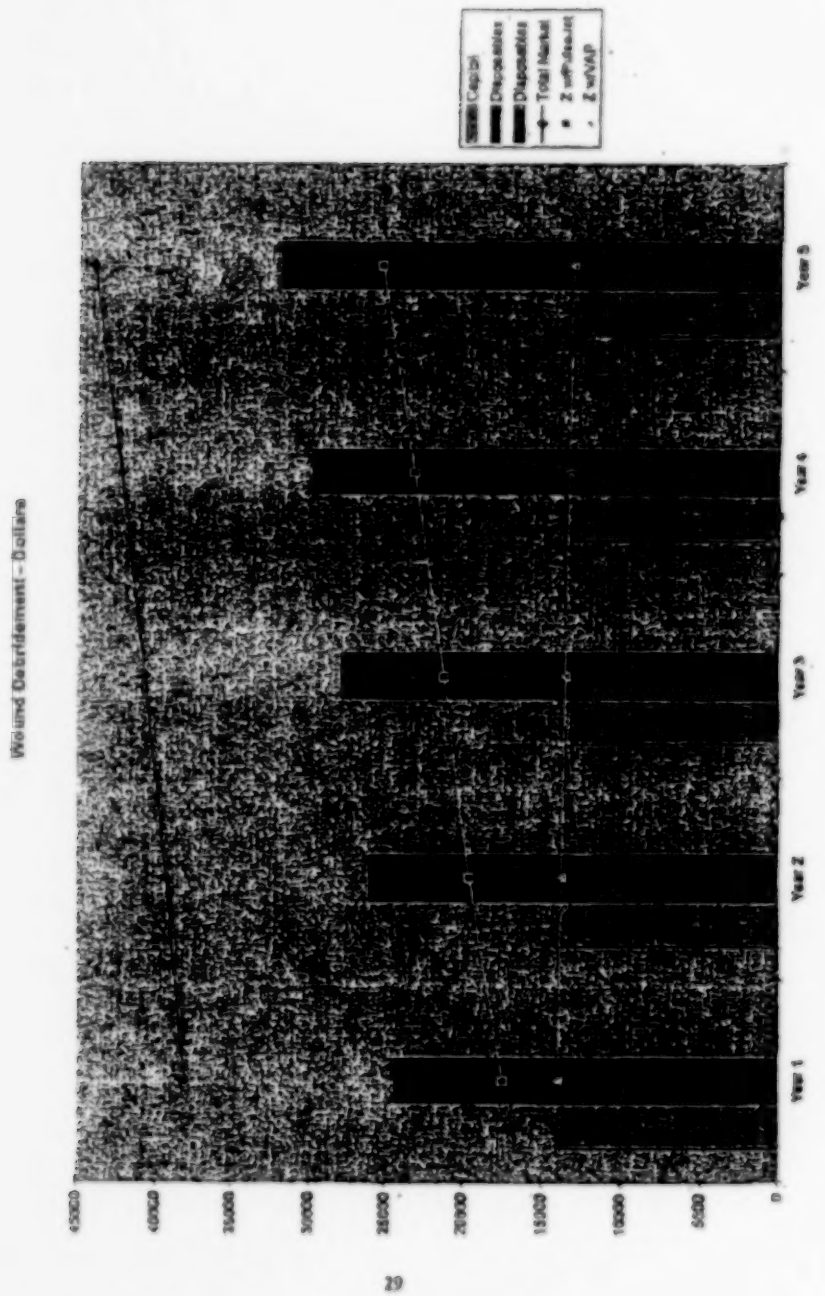
Zimmer Inc.

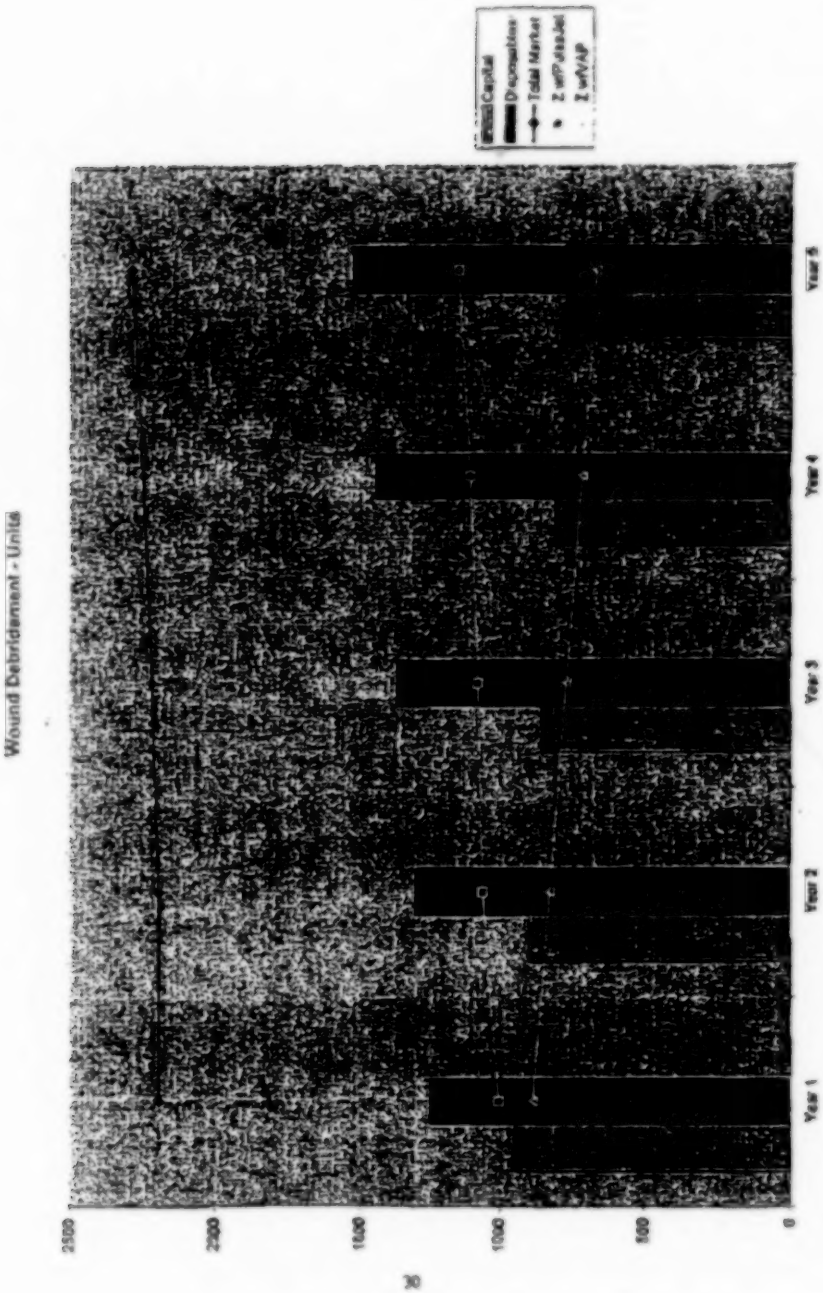
Business Case / Proforma

PulsaJet® Battery Powered Irrigation System

Appendix C

Market Trends


Capital
Disposables
Disposables
Total Market
Wound Debridement - Dollars
Year 1
Year 2
Year 3
Year 4
Year 5
0
5000
10000
15000
20000
25000
30000
35000
40000
45000


Wound Debridement - Units
Total Capital
Depreciation
Total Market
Year 1
Year 2
Year 3
Year 4
Year 5
2500
2000
1500
1000
500
0
$

BATTERY PULSAVAC

TOTAL NUMBERS FOR ALL SPREADSHEETS=U.S. ONLY

YEAR 1	M1*	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	TOTAL
TRAYS	496	488	488	488	496	496	496	501	511	511	519	519	6008
COMP. KITS	679	479	479	479	480	480	480	481	481	481	483	486	5968
ORTHO. TIPS	367	246	243	243	245	243	243	245	243	243	245	243	3038

* =GENERAL RELEASE DATE
=NUMBERS BASED ON 1998 SALES DATA
=NUMBERS ARE REPRESENTED IN BOXES FOR NEW SYSTEM
=Evaluation samples=2000 each: 750=Fan Spray Kit; 750 Shower Spray Kit; 500 Hip Kit

DESCRIPTIONS:		
TRAYS: (W/TIPS)	COMP. KITS: (W/O TIPS)	TIPS:
5160-100	5150-20	5150-75
5160-101	5150-28	-96
5150-200	5150-36	-82
5150-775	5150-300	-83
5150-795	5150-301	-84
5150-752	5150-720	-61
		-85

PULSAVAC AT RISK

YEAR 1 (210 ACCOUNTS)	M1*	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	TOTAL
TRAYS	27	27	27	27	27	27	27	27	27	27	27	27	324
COMP. KITS	393	393	393	393	393	393	393	393	393	393	393	393	4716
ORTHO. TIPS	230	230	230	230	230	230	230	230	230	230	230	230	2760

* =GENERAL RELEASE DATE
=NUMBERS BASED ON 1998 SALES DATA

SWAP-OUT PRODUCT

YEAR 1	M1*	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	TOTAL
TRAYS	14												14
COMP. KITS	197												197
ORTHO. TIPS	114												114

* =GENERAL RELEASE DATE
=NUMBERS BASED ON 1996 SALES DATA

VAR-A-PULSE AT RISK

YEAR 1	M1*	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	TOTAL
TRAYS	454	454	454	454	454	454	454	454	454	454	454	454	5448
COMP. KITS	59	84	84	84	84	84	84	84	84	84	84	84	1013
ORTHO. TIPS	13	13	13	13	13	13	13	13	13	13	13	13	156

* =GENERAL RELEASE DATE
•NUMBERS BASED ON 1996 SALES DATA

INCREMENTAL BUSINESS

YEAR 1	M1*	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	TOTAL
TRAYS	0	7	7	7	15	15	18	20	30	30	38	38	222
COMP. KITS	0	2	2	2	3	3	3	4	4	4	6	6	42
ORTHO. TIPS	0	2	0	0	2	0	0	2	0	0	2	0	8

* =GENERAL RELEASE DATE
=NUMBERS BASED ON 1996 SALES DATA

5% increase in forecast on all other new business after general release

INTERNATIONAL BUSINESS

YEAR 1	Feb 20' M1*	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	TOTAL
TRAYS													0
COMP. KITS													0
ORTHO. TIPS													0

INTERNATIONAL + 20%

* = RELEASE DATE FOR REGIONS

REGIONS:	
CANADA	X
AUSTRALIA/NZ	X
EUROPE	X
KOREA	
TAIWAN	
JAPAN	
SINGAPORE/ REST OF ASIA	X
LATIN AMERICA	X
CEE/EXPORT COUNTRIES	X

TRIP REPORT: 4/5-4/7=PulsaJet
Research Project
Phil Stein/Tim Donaldson

The *purpose* of this trip was to ensure that we, the PulsaJet design team, satisfied all of the points on the rationale, which was uncovered from the field and accounts regarding the current Zimmer battery system: Var-A-Pulse. We keyed in on the following pieces of the project: 1.) design of the handpiece, 2.) battery pack, 3.) power in each of the two settings, 4.) tips, 5.) tip retaining mechanism, 6.) pricing if possible, 7.) public relations for this project and PCD, 8.) any other miscellaneous information, and 9.) trigger mechanism.

Areas visited: Zimmer Maxon: Jackie Ross, an ex-PCD FMS, various associates, sales management and clinical personnel-OR nurse.

Zimmer Carolinas: Gary Cobb, an ex-PCD FMS, Mark Osbourne, various OR personnel, including ortho techs, scrub nurses, circulation nurses, and two Traumatologists (one was Dr. Goetz).

Results of the trip:

1.) All associates, including Gary Cobb and Jackie Ross who have both been close to the Zimmer, Stryker and Davol lavage units for many years, all approved the design of the handpiece. The consensus was, "it is ergonomic and aesthetically pleasing. Additionally and most important, all of the clinical people we spoke with all approved the gun-shaped design.

2.) Battery pack: approval from all. Battery pack external to the handpiece received very positive comments.

We also heard of many accounts from the accounts that the Var-A-Pulse handpieces split apart when tips are put on. We will be addressing this with the batteries out of the handpiece and many clips around the unit.

3.) The new tip was especially of interest to Dr. Goetz, who is a leading traumatologist and is very concerned with flow rates and pressure. This new "trauma tip" will provide more flow at less pressure. We believe that this tip will become very popular in what we believe will be a new and growing market for this system, the trauma market. Phil will be researching papers discussing this topic. Furthermore, more tips like this one might need to be looked at. (Dr. Burgess spoke on this topic at the 1998 Vail Meeting).

Another tip that, by discussions with the associates and clinicians, that will be required for the PT market, is a flexible, narrow and long tip with graduations. Davol has released a tip like this and is taking business with it.

4.) Retaining clip for the tips: This was another large issue with the field and with ALL the OR staff we presented to. This new clip was approved-in theory.

5.) ALL associates and hospital personnel we spoke with mentioned reliability. This system must work EVERY time it is turned on and off with absolutely no leaking. The new design will address this issue.

6.) This meeting, and others with associates in the office, alerted us to the fact that we must not forget the PT department. This area constitutes a great deal of dollars to the associates, especially in the Carolina territory, and positive PR within their accounts. Stryker and Davol have been aggressively pushing their way into our accounts. The Var-A-Pulse has been working well in many PT/Rehab units due to its convenience and portability.

There was not any doubt that the upper speed will be too high for PT applications; however, the lower speed/PSI is still of some concern for various applications. It must be low enough to use in the ER area and most importantly, even lower in the PT department. Tim and Phil discussed various options: 3 speeds, a middle speed, the low PSI level, or a battery pack containing less batteries which will enable the user to release less PSI with 2 Speeds=the "PulsaJet PT". This will be a very important issue to review with the design group and management.

7.) Trigger: We presented 2 choices for evaluation. One was a toggle with 3 detents (high, low and off) and one was a squeeze trigger that changes to high and low with a locking button. Many of the people we met with, found both to be acceptable, but the toggle received most of the positive choices. The decision of where the high, low and off will be in the trigger is still to be decided, however, Dr. Goetz made the point of the off on the bottom to ensure that when the handpiece will be handed off, there will not be any accidental ignition.

Conclusion:

All associates are very anxious to have this product released and able to sell new business and re-convert all of their old business converted by Stryker and Davol. We mentioned that the evaluations will start around the end of the summer or beginning of August 1999. Needless to say, everyone wanted the product as soon as possible. Two accounts we met with were on their way to leaving Zimmer or converting from Davol or Stryker. Both will hang on for the new system and in Kansas City, this new system will enable Zimmer Maxon to convert a series of 12 accounts, many not currently Zimmer lavage accounts. ** Reliability must be a given for any of the above excitement to occur **.

Overall, this was a very positive trip and uncovered important areas for our group to consider and most importantly, it provided us with a sense that we are on the right way to a successful product for Zimmer, the PULSAJET.

H.M. Design, Inc.
3681 Manchester Rd.
Room #303
Akron, Ohio 44319
(330) 644-9616
Fax (330) 644-9619

Attn.: Mr. William J. Donizetti — January 25, 1999
Mr. Tim Donaldson
Zimmer Patient Care Division
200 West Ohio Avenue
P.O. Box 10
Dover, Ohio 44622

Objective:

Our mission is to assist Zimmer Patient Care in recapturing the lost sales, product reliability, sales force confidence, and performance leadership from competitors such as Stryker by providing successful VAR-A-PULSE product design and functionality.

Discussion:

- To develop a VAR-A-PULSE product to be ready for sale by the end of 1999 and ready for the 2000 Academy medical show.

- The new design will have an ergonomic and a totally new appearance to the design.

Scope of services:

This proposal contains the following key performance periods:

1. Preliminary concept development/ component research.

2. Concept refinement/ dimensional design control drawings/ appearance model.

3. Engineering design.

4. Prototyping.

5. SLA/SLS review and revisions.

6. Engineering documentation.

7. Tooling quotation.

8. Tooling engineering/fabrication.

9. Tooling/Product debug.

Phase #1: Preliminary concept development/ component research phase.

Orientation:

A briefing meeting will be held to accomplish the following:

- Allow Zimmer personnel to demonstrate the proper usage, problems and advantages of both the VAR-A-PULSE and competitive units.

*Note: It is imperative that a clearly defined set of marketing objectives be created to insure all design intent is met from the onset of this project. Items such as batteries, ergonomics of product, options for pressure settings, QA inspection, and also manufac-

tured price point are examples of information required prior to starting this program.

Design illustrations:

H.M. Design, Inc. will prepare approximately (4) to (6) preliminary design recommendations in the form of accurately sized colored illustrations to resolve the following issues:

- Totally new appearance to announce the introduction of a new and improved performance.
- Ergonomic form development to facilitate the required usage technique.
- Surface detail for a secure grip.
- Visual detailing will be incorporated to trigger the quality perception so as to overcome the disposable reality.
- Part configuration to support the alternative component assembly recommendations and cost targets.

Preliminary models:

Each design illustration will be supported with preliminary models to offer an initial 3-d evaluation of basic proportion and handling utility.

Internal component research:

Due to the complexity of the overall mechanical function and the potential for revisions to the current configuration, internal components will be researched

concurrently with this phase to insure industrial design is realistic in size, shape, and function.

Phase review meeting:

A review meeting will be held to select the features judged to be most effective in anticipation of a composite design phase.

Estimated phase cost: $24,000
Estimated phase delivery: (2 1/2) Weeks.

Note: Upon determination of preliminary configuration of internal pump mechanism components, it will be necessary to produce rapid prototype components as early as possible to insure integrity of design concepts and schedule. Due to the extreme importance of maintaining schedule it is imperative that engineering prototypes are developed as early as possible to help minimize the product development timeline.

Estimated phase #1 form model budget: $4,000

Zimmer Patient Care Division evaluation phase:

A review meeting will be held with the customer to review form models. At this point the customer must evaluate the models and supply H.M. Design, Inc. with direction in order to proceed into the next phase of product development.

Estimated time: 3 Days

Phase #2: Concept refinement/dimensional design control drawing/ appearance model phase.

The objective of this phase is to reach an early forecast of production and provide a confident static evaluation model prior to incurring detailed engineering and while there is time for management reaction and revisions.

Concept refinement illustration:

The features selected from the range of preliminary designs and any new considerations will be combined and thoughtfully resolved into a final design illustration for Zimmer Patient Care approval to proceed.

Dimensional design control drawings:

The external design features will be dimensionally recorded to serve as a model fabrication drawing and to allow engineering to begin accurate layouts and cost estimations.

Appearance model development:

A static visual model will be prepared to allow the Zimmer Patient Care development team, management and key accounts to evaluate the intended production appearance, size, weight, and handling convenience. This model will be usable for promotional photography.

Estimated phase cost: $14,000
Estimated phase delivery: (2 1/2) Weeks.

Estimated phase #2 appearance model budget: $8,000

Zimmer Patient Care Division approval phase:

A meeting will be held with the customer to review the appearance model. The customer will then have the opportunity to review the model with their sales force and potential customers for any additional recommendations on the design.

Estimated phase: (1) Week.

Phase #3: Engineering design phase.

Preliminary component determination, cost and development:

Per approved styling concept from phase #2. components will be 3d modeled in Pro/ Engineer, assembled, and basic 2d documents will be created for review prior to prototyping.

The following items will be addressed in this phase:

- Housings configuration.
- Internal component configuration.
- Location and assembly of all internal components.
- Material specifications of all components.
- Preliminary specification of all purchased components.
- Preliminary costing of manufactured product.

*Note: H.M. Design, Inc. offers the option of design of electronics if product redesign requires such services and will provide a quotation for this development upon request. We will require Zimmer Patient Care to supply all current motor, electronic information and sample components. H.M. Design, Inc. be responsible for providing mechanical solutions to how these components will function and be assembled in manufacturing.

- Upon approval of assembly and component configuration, basic 2d documents will be created and provided via. CD or e-mail; in IGES or DXF format and (1) set of vellums to Zimmer Patient Care. Component drawings will have overall dimensions and volume of material for gathering tooling/ molding quotes.

- A risk analysis will be performed with guidance from Zimmer Patient Care Division on each component part to determine any potential manufacturing problems prior to releasing product for tooling.

Estimated cost: $42,000
Estimated delivery: (9) Weeks.

Phase #4: Prototype phase.

H.M. Design, Inc. will supervise and coordinate all prototype sources for gathering quotations, and to insure quality of prototypes and integrity of schedule.

H.M. Design, Inc. will utilize the Zimmer Warsaw prototyping facility when possible to minimize prototyping cost. However, if scheduling becomes a conflict

other prototype recourses will be utilized to maintain the schedule.

Engineering model:

Model / Pattern makers will be utilized during this phase to fit and aid in the debug of the prototype units.

- H.M. Design, Inc. will supervise model fabrication and review all prototype components prior to delivery of model to Zimmer Patient Care Division.

- Various prototyping options and quotations will be presented based on creating a functional/ aesthetic model prior to releasing components for fabrication of production tooling.

Estimated engineering supervision cost: $3,000
Estimated phase delivery: (2) weeks

Estimated engineering model cost: $4,000 per model.

Phase #5: SLA / SLS Review and revisions.

Engineering model review / Component revisions.

*It is important to note that the debugging of the product design performance may require the fabrication of multiple prototype units prior to releasing for production tooling.

- Based on the results of the prototypes, the components will be modified and revised as necessary.

- Final prototypes will be reviewed with Zimmer Patient Care Division prior to release for prototype field-testing.

Estimated supervision cost: $3,000
Estimated phase delivery: (2) weeks.

Estimated additional model cost: $2,000 per model.

Phase #6: Engineering documentation phase.

- Based on results of prototyping phase, 3D models will be revised as necessary prior to detailing.

- 2d documentation will be created of all components designed by H.M. Design, Inc. for fabrication of production tooling. It is assumed that all tooling will be created utilizing 3d Pro/ Engineer data thus, component documentation will consist of overall dimensions and key fits needing to be checked in quality assurance inspection of components during manufacturing. If complete 2d documentation of components is required, additional cost will be quoted to Zimmer Patient Care Division at this time.

- Assembly drawings will be created with bill of materials.

- All final documentation will be supplied as (1) set of vellums, I.G.E.S. or DXF format of 2d

data and all 3d data will be delivered as Pro/ Engineer models; I.G.E.S. or DXF format via. CD or e-mail to Zimmer Patient Care and toolmaker of choice.

Estimated phase cost: $6,000
Estimated phase delivery: (2-3) Weeks.

Phase #7: Tooling quotations.

- Mold quotation specification sheets will be created and reviewed prior to release for quotations. To insure optimum tooling configuration based on supplied estimated production quantities, and to insure uniformity in submitted quotations.

- Upon approval of tooling specifications, Mold quotations will be obtained for review and approval with Zimmer Patient Care Division.

- A mold report summary will be submitted to Zimmer Patient Care Division. This report will list all mold makers, cost, and delivery of each mold.

Estimated phase cost: $3,000
Estimated phase delivery: (1) Week.

Phase #8: Tool Engineering / Fabrication phase.

To monitor tooling development, to insure the integrity of the schedule and quality of production tooling.

Upon the selection of tooling venders and the release for tooling the follow items will be addressed:

- Preliminary tool design review will be held between the molder and the toolmaker and H.M. Design, Inc.

- Periodic visits will be made to the toolmakers to insure the integrity of the tooling and the schedule.

- A report will be submitted monthly on the status of each mold.

Estimated phase cost: $11,000
Estimated phase delivery: (12) Weeks.

Phase #9: Tooling / Product debug.

Upon completion of production tooling the following items will be addressed:

- Production sampling will be monitored to insure optimum part quality and cycle time. Recommendations will be made for any proposed revisions to tooling prior to production molding.

- All tooling revisions will be monitored to insure integrity of production tooling and schedule.

Estimated phase cost: $6,000
Estimated phase delivery: (3) Weeks.

Summary:

Phase #1: Preliminary concept development / component research.	$24,000	3 weeks

Zimmer Patient Care Division evaluation phase:		1 week
Phase #2: Concept refinement / Control drawing.	$14,000	3 weeks
Zimmer Patient Care Division approval phase:		1 week
Phase #3: Engineering design phase.	$42,000	9 weeks
Phase #4: Prototype phase	$3,000	2 weeks
Phase #5: SLA / SLS Review and Revisions.	$3,000	2 weeks
Phase #6: Engineering documentation phase.	$6,000	2-3 weeks
Phase #7: Tooling quotations.	$3,000	1 week
Phase #8: Tool engineering / fabrication phase.	$11,000	12 weeks
Phase #9: Tooling / Product debug.	$6,000	3 weeks
Estimated Engineering Budget:	**$112,000**	**40 weeks**

Phase #1: Model budget.	$4,000
Phase #2: Model budget.	$8,000
Phase #4: Model budget. (One model only)	$4,000
Phase #5: Model revision budget. (One model only)	$2,000

Estimated Model Budget:	$18,000

Estimated project budget total: **$130,000**

Items required prior to project start:

- Samples of competitive units.
- Signed acceptance of this quotation and purchase order.
- Existing prototypes and engineering documentation available.
- Sample motors and existing components available for prototypes.
- List of specific marketing objectives/ specifications and estimated price point.

We would like to thank you for allowing us the opportunity to submit this quotation and look forward to working with you on this program.

Sincerely

Detlev F. (Frank) Smith
President

Donald R. Wright
Vice President

Terms:

Any additional project management activities will be billed on a time and material basis at $50/hr. with prior approval of the customer.

All Prototype and production tooling costs will be billed directly to the customer by the vendors providing those services.

Travel expenses will be billed separately with prior approval of the customer.

Any changes to product design or project criteria may affect delivery and cost.

Our product design will reflect a sincere effort to be error free and will be checked prior to release to the customer, who will assume the responsibility for final approval and release to tooling.

This quotation will remain valid for a period of 30 days.

Expenses are billed monthly and are due net 15 days.

Late payments are subject to a 2% late fee after 10 days. (24% per year.)

All applicable patent information, U.L. approvals, product testing, and liabilities remain the customer's responsibility.

(Customer's name):
Accepted by:

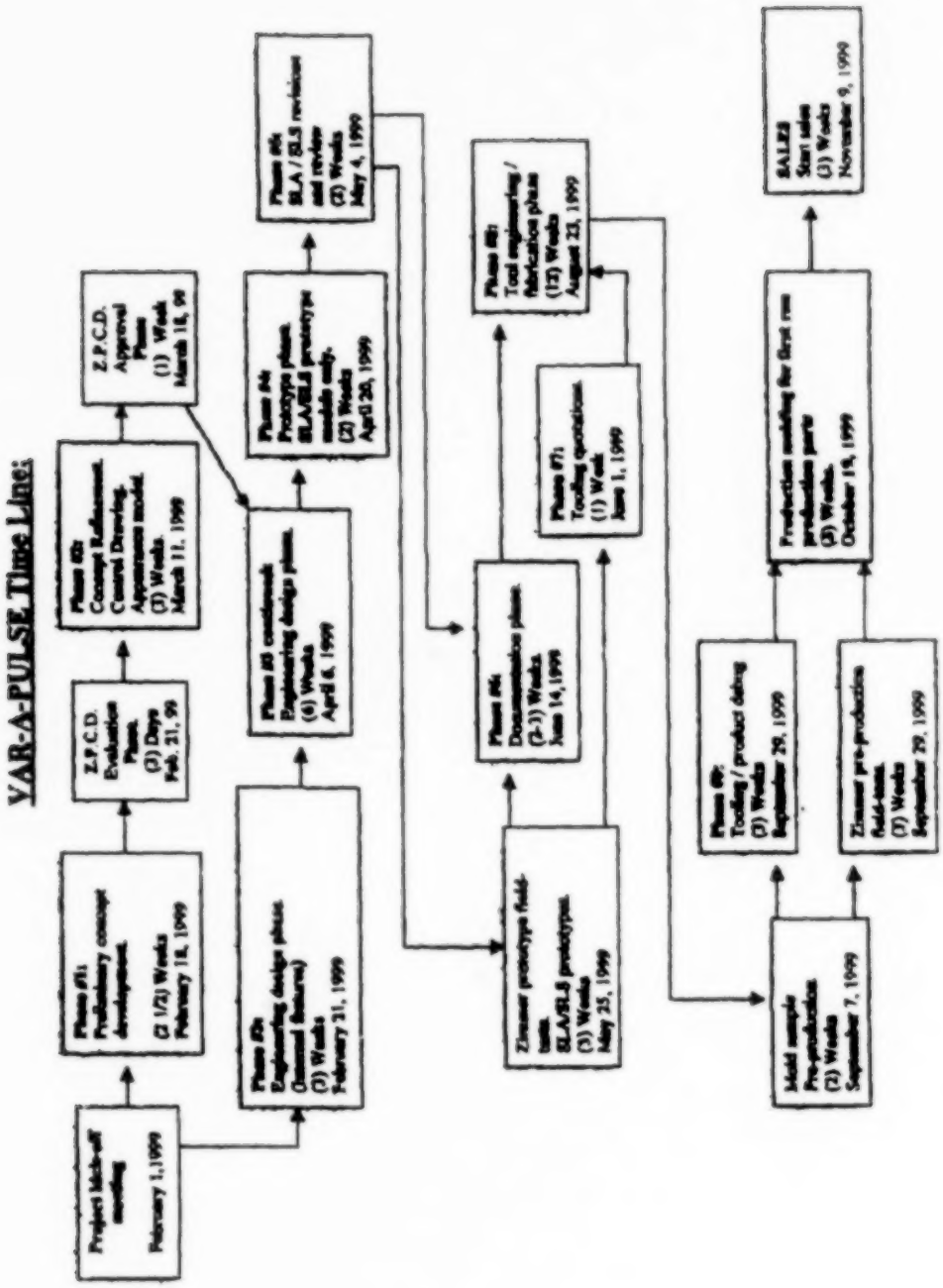
_____

_____

Title

_____

Date


VAR-A-PULSE Time Line:
Project kickoff meeting
February 1, 1999
Phase #1:
Preliminary concept development.
(2 1/2) Weeks
February 18, 1999
Phase #2:
Engineering design phase.
Optional features)
(3) Weeks
February 21, 1999
Z.P.C.D. Evaluation Phase.
(3) Days
Feb. 21, 99
Phase #3:
Engineering design phase.
(6) Weeks
April 4, 1999
Phase #3 continued:
Engineering design phase.
(6) Weeks
April 4, 1999
Phase #5:
Concept Refinement.
Control Drawing.
Appearance model.
(3) Weeks.
March 11, 1999
Z.P.C.D. Approval Phase.
(1) Week
March 18, 99
Phase #4:
Prototype phase.
SLA/SLS prototype models only.
(2) Weeks
April 28, 1999
Phase #4:
SLA / SLS revision and review
(2) Weeks
May 4, 1999
Zimmer prototype fluid tests
SLA/SLS prototypes
(3) Weeks
May 25, 1999
Phase #6:
Documentation phase.
(2-3) Weeks
June 14, 1999
Phase #7:
Tooling quotation.
(1) Week
June 1, 1999
Phase #8:
Tool engineering / fabrication phase
(12) Weeks
August 23, 1999
Model sample Pre-production
(2) Weeks
September 7, 1999
Phase #9:
Tooling / product debug
(5) Weeks
September 29, 1999
Zimmer pre-production fabrication
(5) Weeks
September 29, 1999
Production molding for first run production parts
(3) Weeks.
October 19, 1999
SALES
Start sales
(3) Weeks
November 9, 1999

H.M. Design, Inc.
3681 Manchester Rd.
Room #303
Akron, Ohio 44319
(330) 644-9616
Fax (330) 644-9619

Attn.: Mr. Tim Donaldson
Zimmer Patient Care
200 West Ave.
Dover, Ohio 44622

January 29, 1999

Subject: 1-29-99 meeting minutes.

Attending:

Mr. Tim Donaldson - Zimmer Patient Care
Mr. Bill Donizetti - Zimmer Patient Care
Mr. Donald Wright - H.M. Design, Inc.
Mr. Rick May - H.M. Design, Inc.
Mr. Bill Brazis - H.M. Design, Inc.

Per our 1-29-99 meeting at Zimmer Patient Care, the following items were concluded:

- The current market for wound debridement systems is making a transition from capital equipment to less expensive and more space efficient battery operated units.

- The current understanding of the user's perception of product quality, in comparison to other competitive units, tends to key in on Fluid pressure. The current VAR-A-PULSE unit has more power or pressure than any of the competitive units, but the quality perception is a combination of impact, shot size or speed of

saline use and in some respects the actual noise level of the unit. It must be noted that the product should not be designed to eliminate motor/ mechanical noise.

- A key selling feature for the operating room purchasing agent is the fact that the unit contains (8) AA batteries that are typically removed from the unit for personal use prior to disposing of unit. Batteries should be secure but easily removable.

- Trigger design should be located for finger activation similar to a handgun, thumb operation has been described as awkward. Trigger mechanism should allow for (2) speeds: a (4) battery and a (8) battery speed. Trigger should also be lockable in both positions for a extended use during surgery.

- Product currently utilizes (8) styles of spray tips, new product must be able to accept all of the current spray tips with no revision to current tip design to avoid compatibility problems with product already in the field. New product design should eliminate the problem of spray tips detaching from gun during use, while allowing for the replacement of tips during surgery in a timely fashion.

- Current gun design has been described as "bottom heavy" due to location of batteries, a more balanced unit should be a development goal. It should also be noted that the current design does not fit into pockets of skirts utilized in surgery thus the gun is often placed on the pa-

tient when not in use and has a tendency to fall off to the floor.

- Batteries may be remotely located for better gun balance, design cannot have tubes run through the battery box, due to current Stryker patents, but may be fastened to the outside. It must also be noted that Zimmer Patient Care does not have the capability to coextrude the wiring with the tubing as seen on competitive units therefore this type of design would have to be verified with the research of vendors and cost estimation of manufacturing and assembly. It may also be possible to have a separate wire and mount batteries to a belt clip unit or placed on the floor of the operating room.

- Fasteners or screws should be avoided in the design to minimize cost and assembly. Also, several components will be sonic welded and meticulous attention to energy director design must be taken into consideration due to past problems with leaks due to poor welds.

- Units cannot leak, saline solution tends to react quickly with batteries and electronics causing corrosion and expulsion of a black fluid which is unacceptable to product performance. For this reason, all contacts should be minimized in size to avoid exposure to saline.

- Product does not need to be waterproof, but should be extremely water resistant. Normal product use dictates that the unit should not be

submerged and warns users of this on packaging.

- Normal product use is about a (5) minute timeframe, product must run for (15) minutes in testing on batteries, the current unit runs for about (45) minutes.

- Units will be sterilized either with gamma or ETO.

- Current supplied prototype uses a dual valve configuration taken from a Stryker unit, in final design concept this will have to be separate components due to existing competitor patent.

Items required for the progression of product development:

- Any available video documentation of actual product and/ or competitor product use, storage, etc.

- Engineering documentation and bill of materials on current VAR-A-PULSE unit.

- Engineering documentation and sample parts of all (8) VAR-A-PULSE nozzles.

- Information on any motors, gears, purchased components already researched and sample parts if available.

- Next production run of VAR-A-PULSE assembly at Zimmer Patient Care schedule for evaluation of production equipment and practices by H.M. Design, Inc.

- An operation room use of the VAR-A-PULSE and/ or competitive unit demonstration. We would like to be able to have (3) people present, permission to photograph activity, and would also like to encourage this activity to be held locally to minimize travel expenses.

Please review and confirm the information in this document. Our intent is to insure the accuracy of all information passed on to us, therefore proper review and timely reply to this document will be greatly appreciated.

Thanks,

Donald Wright
H.M. Design, Inc.

H.M. Design, Inc.
3681 Manchester Rd.
Room #303
Akron, Ohio 44319
(330) 644-9616
Fax (330) 644-9619

Attn.: Mr. Tim Donaldson
Zimmer Patient Care
200 West Ave.
Dover, Ohio 44622

February 17, 1999

Subject: 2-15-99 and 2-16-99 meeting minutes.

Attending: 2-15-99 Meeting
Mr. Todd Martin - Zimmer Patient Care
Mr. Rick May - H.M. Design, Inc.
Mr. Frank Smith - H.M. Design, Inc.

Attending: 2-16-99 Meeting
Mr. Tim Donalson-Zimmer Patient Care
Mr. Rick May - H.M. Design, Inc.
Mr. Frank Smith - H.M. Design, Inc.
Mr. Roger Ramsey - H.M. Design, Inc.

Per our 2-15-99 meeting at H.M. Design, Inc., the following items were concluded:

- A product development history was recapped with Todd Martin to review the findings and engineering criteria that was established by Zimmer Patient Care over the past 1 ½ years.

- The inlet hose I.D. was the driving force to determine the best pump and piston configuration. The main criteria was to eliminate as many flow restrictions and still achieve a velocity of 2000ml of fluid per min.

- The present prototyped pump will drive approximately 1380ml./min.

- The current prototype has ½" of travel for the piston on the pump mechanism.

- There is an 8:1 gear ratio between the large pump gear (80 teeth) and the small drive gear (10 teeth).

- A metal gear shaft will need to be used on the pump gear, because of the heat buildup from the high number of RPMs from the motor. This was a problem that the competition (Stryker) had and was resolved with a metal shaft.

- A duckbill valve will be used for the irrigation port of the pump. This valve was chosen because of the pulsating feel it gives to the saline solution during operation.

- If leaking from the tip appears to be a problem the duckbill valve will be replaced with a preloaded duckbill valve.

- Todd martin will fax H.M. Design, Inc., the pressure specifications for determining the proper valves to use.

- The pump should be located as close to the tip connector as possible. This will help reduce the amount of leaking fluid form the tip of the device.

- The current prototype utilizes (l) O-ring. The new design will be started with (2) O-rings to minimize the leaking. Depending on cost a quad ring may be utilized.

- It was advised by Todd Martin that an in line fuse be added to the assembly to prevent the motor from overheating and possibly injuring the operator.

Per our 2-16-99 meeting at H.M. Design, Inc., the following items were concluded:

- There will be no designs with the batteries in the handle. This information was arrived from customer input from the Academy show and this is what the competition is currently during with their design.

- The battery pack will be (2) rows of (4) batteries. The battery pack will have a hook and approximately 4ft. of wire to attach to the gun.

- There will be no wire connector to the battery pack as on the Stryker gun.

- The design team will look into adding an in-line fuse to the electronics for safety.

- **The existing tips must be utilized for this design.** The design will utilize the tapered press fit without any O-rings. The design team will develop a locking mechanism to help retain the existing tip design.

- Marketing and sales input / direction to the following design concepts.

  - In general a "rectilinear shape" was preferred.

  - No pivoting mechanism to the handle. Price point is too sensitive for this feature.

  - Design concept #1: Was the least preferred. Marketing and sales did like the rib design features in the handle.

  - Design concept #5: Was liked, but will need to remove the protrusion for the motor.

  - Design concept #6: Need a form model to help understand the concept of the shape and multiple hand positioning. There are some concerns that the design may look too much like the competition.

  - Design concept #2: One of the favorite designs. Needs a larger trigger.

  - Design concept #3: One of the favorite designs. Liked the large trigger but not this large. Marketing preferred the horizontal design feature line for use as an improved grip when holding the gun by the back instead of the handle.

- Keep all handles as small as possible. Note that the trigger mechanism and the tubing may drive the size of the handle.

- The preferred cycle for the trigger operation is as follows:

  - Low to high speed by squeezing the trigger and having a secondary speed lock. This is the same way the Stryker unit operates.

  - The concept of the electronic switch was liked. If the price of the switch is comparable to the contacts on the existing unit. Marketing did not like the cycling of the electronics; Marketing did not want the operator to cycle through high to turn off the unit.

- The next meeting will be at Zimmer Patient Care in Dover, Ohio. Wednesday February 24, 1999 at 10:00 am.

Items required for the progression of product development:

- Todd Martin to fax H.M. Design, Inc., the pressure specifications for determining the proper valves to use in the design of the pump.

- Existing documentation on the Var-a-pulse pump components and a sample of non-assembled components.

Please review and confirm the information in this document. Our intent is to insure the accuracy of all information passed on to us, therefore proper review

and timely reply to this document will be greatly appreciated.

Thanks,

Frank Smith
H.M. Design, Inc.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arnett et al. Art Unit: 3767

App. No: 11/563,504 Examiner: Bumgarner, M.N.

Filed: 27 NOV 2006 Conf. No.: 1074

Title: SURGICAL/MEDICAL IRRIGATING HANDPIECE WITH VARIABLE RATE PULSE PUMP, VARIABLE SPEED MOTOR FOR ACTUATING THE PUMP, INTEGRATED SUCTION AND REMOTE BATTERY PACK

RESPONSE TO OFFICE ACTION

This paper is submitted in response to the Office Action for the above-identified application mailed 3 December 2010. This Response is submitted simultaneously with a Request For Continued Examination for the application.

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Amendments To The Claims

The following is a complete listing of all claims presently in this application, including the Previously Presented claims and statements identifying the claims amended by way of this Response.

Claims 1-30 (Canceled).

31. (Original) A medical irrigator comprising:

a housing shaped to be hand held and having a front end, the front end having a fluid outlet opening;

a tip assembly that extends forward from the front end of said housing, said tip assembly having an outlet tube in fluid communication with the housing fluid outlet opening and a suction tube;

an inlet tube extending to said housing;

a pulse pump capable of operating at a variable rate disposed in said housing that opens to the housing front end, said pump configured to receive fluid from said inlet tube and discharging the fluid through the fluid outlet opening;

a single electric motor disposed in said housing and connected to said pump for actuating said pump, said motor operable at variable speeds to control the pumping rate of said pump;

a control assembly disposed in said housing to regulate the speed of said motor;

a flexible suction tube that is in fluid communication with said tip assembly suction tube and that extends away from said housing;

a battery pack separate from said housing; and

a flexible conductor assembly extending from said battery pack to said housing for supplying energy stored in said battery pack to said motor.

32. (Original) The medical irrigator of Claim 31, wherein said control assembly has a switch that is moveably mounted to said housing, said control assembly configured so that:

when said switch is in a first position, said control assembly does not supply an energization signal to said motor;

when said switch is in a second position, said control assembly supplies a first energization signal from said battery pack to said motor; and

when said switch is in a third position, said control assembly supplies a second energization signal from said battery pack to said motor.

33. (Currently Amended) The medical irrigator of Claim ~~31~~ 32, wherein said switch is configured to move:

from the first position and to the second position; and

from the second position to the third position.

34. (Currently Amended) The medical irrigator of Claim 31, wherein:

said housing is formed to have: a handle; and a barrel integral with and located above said handle that extends forward from said handle, said barrel ~~having~~ being shaped to form the housing front end including the housing fluid outlet opening; and

said motor is located in said housing handle.

35. (Previously Presented) The medical irrigator of Claim 31, wherein said tip assembly suction tube surrounds said tip assembly outlet tube.

36. (Original) The medical irrigator of Claim 31, wherein said inlet tube extends from said battery pack to said housing.

37. (Currently Amended) The medical irrigator of Claim 31, wherein:

the housing front end is formed with a fluid inlet opening;

said tip assembly suction tube is connected to the housing fluid inlet opening;

a suction hose is disposed in said housing and extends from the housing fluid inlet opening and to said flexible suction tube ~~is connected~~ so that said suction hose provides a fluid communications path from said tip assembly suction tube to said flexible suction ~~hose~~ tube.

38. (Original) The medical irrigator of Claim 31, wherein said housing and said tip assembly are

formed with complementary features for releasably holding said tip assembly to the housing front end.

39. (Currently Amended) A medical irrigator comprising:

a housing shaped to have a front end;

a pulse discharge pump that operates at a variable rate disposed in said housing having an inlet and discharge conduit, the discharge conduit opening towards the front end of said housing;

an inlet line that extends into said housing that is in fluid communication with the pump inlet;

a single electric motor disposed in said housing and connected to said pump to actuate said pump, said motor operating at variable speeds to regulate the pumping rate of said pump;

a tip assembly that extends from the front end of said housing, said tip assembly having an outlet tube that is in fluid communication with the pump discharge conduit and a suction wand;

a flexible suction tube that is in fluid communication with said tip assembly suction wand;

a battery pack separate and spaced from said housing that contains at least one battery that stores energy for energizing said motor;

a flexible cable that extends from said battery pack to said housing for supplying energy from said battery pack to said motor; and

a control assembly integral with said housing to which said cable is connected, said control assembly having a switch member moveably mounted to said housing and said control assembly being configured to apply a variable energization signal from said battery pack to said motor so as to control the speed of said motor and regulate the pumping rate of said pump.

40. (Previously Presented) The medical irrigator of Claim 39, wherein:

said cable includes a first conductor over which a first energization signal is available from said battery pack and a second conductor over which a second energization signal is available from said battery pack; and

said control assembly is configured so that said switch member can be selectively positioned to: connect neither of said cable conductors to said motor; connect the first said cable conductor to said motor; or connect the second said cable conductor to said motor.

41. (Original) The medical irrigator of Claim 40, wherein said control assembly is configured to sequentially move from the position in which neither said cable conductors are connected to said motor to the position in which said first cable conductor is connected to said motor and to the position in which the second said cable conductor is connected to said motor.

42. (Original) The medical irrigator of Claim 39, wherein said pump is a reciprocating pump.

43. (Original) The medical irrigator of Claim 39, wherein said inlet line extends from said battery pack to said housing.

44. (Original) The medical irrigator of Claim 39, wherein said tip assembly is constructed so that said outlet tube is disposed in said suction wand.

45. (Original) The medical irrigator of Claim 39, wherein:

a suction hose having opposed ends is disposed in said housing;

said suction wand is connected to a first end of said suction hose; and

said flexible suction tube is connected to a second end of said suction hose.

46. (Original) A medical irrigator, said irrigator comprising:

a housing having a front face;

a tip assembly that extends from the front face of said housing, said tip assembly including an outlet tube and a suction wand;

a pulse discharge pump disposed in said housing that operates at a variable rate, said pump having an inlet and an outlet, the outlet opening into the front face of said housing so as to be in fluid communication with said tip assembly outlet tube;

a flexible suction tube that is in fluid communication with said tip assembly suction wand, said flexible suction tube extending away from said tip assembly;

a single, variable speed electric motor disposed in said housing connected to said pump for actuating said pump at variable rates;

a battery pack separate from said housing containing at least one battery;

a flexible cable that extends from said battery pack to said housing, said flexible cable having at least one conductor over which an energization signal from said at least one battery is supplied; and

a control assembly attached to said housing and connected between said at least one conductor and said motor for supplying a variable potential energization signal to said motor, said control assembly having a single switch member that is moveably attached to said housing that selectively makes/breaks a connection between said at least one conductor and said motor and that establishes the potential of the energization signal supplied to said motor.

47. (Currently Amended) The medical irrigator of Claim 46, wherein:

said cable has a first conductor over which a first energization signal is available from said at least one battery and a second conductor over which a second energization signal is available from said at least one battery; and

said control assembly is configured so that <u>said</u> switch member can be selectively positioned to: con-

nect neither of said cable conductors to said motor; connect the first said cable conductor to said motor; or connect the second said cable conductor to said motor.

48. (Original) The medical irrigator of Claim 47, wherein said control assembly has a first contact to which said first cable conductor is attached and a second contact to which said second cable conductor is attached and said contacts are statically mounted to said housing.

49. (Currently Amended) The medical irrigator of Claim 46, wherein:

the housing front face is formed with a fluid inlet opening in which said tip assembly suction wand is received;

a suction hose is disposed in said housing and extends from the fluid inlet opening; and

said <u>flexible</u> suction tube is connected to said suction hose.

50. (Original) The medical irrigator of Claim 46, wherein said tip assembly is constructed so that said outlet tube is disposed in said suction wand.

REMARKS

This paper is submitted in response to the Office Action for the above-identified application mailed 3 December 2010.

Under cover of the Office Action, objections to Claims 33 and 34 were entered.

The claims of this application were also subjected to a double patenting rejection in view of the Applicants' US Pat. No. 7,144,383 and US Pat. No. 4,692,140 to Olson. In regard to the double patenting rejection, it was stated in the Office Action that the Applicants' previously filed Terminal Disclaimer was not accepted.

Also, in the Office Action it was stated that a number of the documents cited in the Information Disclosure Statement filed 6 December 2010 did not appear to be in the Office's file for the applications from which this application claims priority. Accordingly, it was indicated in the Office Action that a number of the cited documents were not considered.

With regard to the documents cited but not submitted in the 6 December 2010 Information Disclosure Statement, the Applicants understand that these documents were previously submitted to the Office during the prosecution of the applications from which this application claims priority. The Applicants therefore continue to assert that per 37 CFR Sec. 1.98(d) to provide duplicate copies of the documents.

However, the undersigned representative will now work with the Examiner to determine if copies of the cited documents are presently in the Office's files. If copies are not available, the Applicants in a new Information Disclosure Statement, will provide additional copies of these documents.

Under cover of this paper amendments are made to Claims 33, 34, 37, 39, 47 and 49.

The amendment to Claim 33 changes the dependency of this claim from Claim 31 to Claim 32. This amendment rectifies the matter giving rise to the objection to this claim.

Claim 34, now recites that the barrel portion of the housing is "shaped to form the housing front end including the housing fluid outlet opening." Claim 31 recites that the housing includes a front end with a fluid outlet opening. Accordingly it is respectfully submitted that Claim 31 provides sufficient antecedent basis for the claim elements recited by Claim 34.

It is therefore submitted that the claim amendments rectify the matters giving rise to the claim objections. These objections should now be withdrawn.

Claims 37, 39 and 49 are amended to enhance the stated relationship of the claim elements.

Claims 47 is amended to correct an informality.

A new Terminal Disclaimer with the necessary fee is filed herewith. It is submitted that this Terminal Disclaimer properly disclaims the term of this patent extending beyond the term of US Pat. No. 7,144,383.

It is therefore submitted that this Terminal Disclaimer should be acceptable. Further, the acceptance of this Terminal Disclaimer serves to overcome the double patenting rejection. Withdrawal of this rejection is now requested.

It is submitted that with these amendments and the submission of the Terminal Disclaimer, the matters giving rise to the outstanding objections and re-

jections have been rectified. The Applicants submit that this application is in condition for allowance.

However, as mentioned above, it is respectfully requested that the Examiner delay review of this application, and the issuance of a Notice of Allowance, until the documents the previously cited for potentially being material have been considered.

Respectfully submitted,

June 2, 2011

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Enclosure: Terminal Disclaimer

[4] ['504 Patent Application Prosecution History (Excerpt)]

9. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 47, the claim recites the terms "a first conductor" and a second conductor". Claim 47 depends upon claim 46. Claim 46 recites the term "at least one conductor". It is unclear whether the terms of claims 46 and 47 refer to the same elements or different elements.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 31-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grulke et al (US

5,046,486), and further in view of Drews (US 4,817,599).

In regards to claim 31, Grulke et al teaches a medical irrigator (Figures 1-11) comprising:

a. a housing (housing [11]) shaped to be hand held and having a front end, the front end having a fluid outlet opening (Figure 2)

b. a tip assembly (tip unit [125]) that extends forward from the front end of said housing, said tip assembly having an outlet tube (irrigation tube [153]) in fluid communication with the housing fluid outlet opening and a suction tube (large tube [144])

c. an inlet tube (irrigant liquid supply hose [42]) extending to said housing

d. a pulse pump (pulsed pump [20]) disposed in said housing that opens to the housing front end (Figure 4), said pump configured to receive fluid from said inlet tube and discharging the fluid through the fluid outlet opening

e. a single motor (motor head [204]) disposed in said housing and connected to said pump for actuating said pump

f. a flexible suction tube (suction tube [124]) that is in fluid communication with said tip assembly suction tube and that extends away from said housing

Grulke et al is silent about whether the pump is capable of operating at a variable rate, does not teach that the motor is an electric motor since the motor is a gas pressure-driven motor (Abstract), is silent about whether the motor is operable at variable speeds to control the pumping rate of the pump, is silent about a control assembly disposed in said housing to regulate the speed of said motor, is silent about a battery pack separate from said housing, and is silent about a flexible conductor assembly extending from said battery pack to said housing for supplying energy stored in said battery pack to said motor. Drews teaches a medical irrigator (Figures 1-4) comprising a pump (pump [20]) that is capable of operating at a variable rate, an electric motor (motor [34]), wherein the motor is operable at variable speeds to control the pumping rate of the pump, a control assembly (control switch [36]) disposed in a housing (pump unit [12]) to regulate the speed of said motor, a battery pack (battery power supply [14b]) separate from the housing, and a flexible conductor assembly (electrical control cable [40]) extending from said battery pack to said housing for supplying energy stored in said battery pack to said motor. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the irrigator, of Grulke et al, with the pump operating at a variable rate, the gas pressure-driven motor being substituted with an electric motor, the motor operable at variable speeds, a control assembly to regulate the speed of the motor, a battery pack separate from the housing, and a flexible conductor assembly for supplying energy stored in the battery pack to the motor, as taught by Drews, as allowing the pump to operate at a variable rate or speed by an electric motor operating at variable

speeds will allow the user the ability to vary the amount of fluid pressure applied to the patient at a given time based on the type of procedure being performed, such as the infusion of an intravenous medium or to and fro washing of a cortex and/or nucleus of the eye in extracapsular cataract surgery (Abstract)(column 3, lines 56-66).

In regards to claims 32 and 33, in a modified irrigator of Grulke et al and Drews, Grulke et al does not teach a control assembly. Drews teaches that the control assembly has a switch [36] that is moveably mounted to said housing, said control assembly configured so that:

> a. when said switch is in a first position (starting position when switch is not used), said control assembly does not supply an energization signal to said motor
>
> b. when said switch is in a second position (emulsifying position [36a]), said control assembly supplies a first energization signal from said battery pack to said motor
>
> c. when said switch is in a third position (infusion position [36b]), said control assembly supplies a second energization signal from said battery pack to said motor
>
> d. wherein said switch is configured to move:
>
> > i. from the first position to the second position

ii. from the second position to the third position

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the control assembly, of the modified irrigator of Grulke et al and Drews, with a switch, as taught by Drews, as the speed of the motor and pump is proportional to the amount of pressure applied by the user to the switch to provide for variable speed operation of the motor and pump (column 3, lines 56-62).

In regards to claim 34, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches wherein:

a. said housing is formed to have: a handle (handle [12]); and a barrel (barrel [13]) integral with and located above said handle that extends forward from said handle, said barrel being shaped to form the housing front end including the housing fluid outlet opening (Figure 2)

b. said motor is located in said housing handle (Figures 2 and 4)

In regards to claim 35, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches that said tip assembly suction tube surrounds said tip assembly outlet tube (Figure 9).

In regards to claim 36, in a modified irrigator of Grulke et al and Drews, Grulke et all does not teach a battery pack. Drews teaches that an inlet tube (tube [28]) extends from the battery pack [14b] to the hous-

ing [12] (Figure 1). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the inlet tube, of the modified irrigator of Grulke et al and Drews, to extend from the battery pack to the housing, as taught by Drews, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70.*

In regards to claim 37, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches wherein:

> a. the housing front end is formed with a fluid inlet opening (Figure 2)
>
> b. said tip assembly suction tube is connected to the housing fluid inlet opening (Figure 9)
>
> c. a suction hose (suction hose [100]) is disposed in said housing and extends from the housing fluid inlet opening and to said flexible suction tube so that said suction hose provides a fluid communications path from said tip assembly suction tube to said flexible suction tube (Figure 2)

In regards to claim 38, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches that said housing and said tip assembly are formed with complementary features (insert [127] and body [128]) for releasably holding said tip assembly to the housing front end.

In regards to claim 39, Grulke et al teaches a medical irrigator (Figures 1-11) comprising:

a. a housing [11] shaped to have a front end (Figure 2)

b. a pulse discharge pump [20] disposed in said housing having an inlet and discharge conduit (caps [192][193]), the discharge conduit opening towards the front end of said housing (Figure 4)

c. an inlet line [42] that extends into said housing that is in fluid communication with the pump inlet

d. a single motor [204] disposed in said housing and connected to said pump to actuate said pump

e. a tip assembly [125] that extends from the front end of said housing, said tip assembly having an outlet tube [153] that is in fluid communication with the pump discharge conduit and a suction wand [144]

f. a flexible suction tube [124] that is in fluid communication with said tip assembly suction wand

Grulke et al is silent about whether the pump operates at a variable rate, does not teach that the motor is an electric motor since the motor is a gas pressure-driven motor (Abstract), is silent about whether the motor operates at variable speeds to regulate the pumping rate of the pump, is silent about a battery pack separate and spaced from said housing that contains at least one battery that stores energy for energizing said motor, a flexible cable that extends from

said battery pack to said housing for supplying energy from said battery pack to said motor, and a control assembly integral with said housing to which said cable is connected, said control assembly having a switch member moveably mounted to said housing and said control assembly being configured to apply a variable energization signal from said battery pack to said motor so as to control the speed of said motor and regulate the pumping rate of said pump. Drews teaches a medical irrigator (Figures 1-4) comprising a pump (pump [20]) that operates at a variable rate, an electric motor (motor [34]), wherein the motor operates at variable speeds to regulate the pumping rate of the pump, a battery pack (battery power supply [14b]) separate from the housing, a flexible cable (electrical control cable [40]) extending from said battery pack to said housing for supplying energy stored in said battery pack to said motor, and a control assembly with a switch (control switch [36]) integral with a housing (pump unit [12]) to regulate the speed of said motor. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the irrigator, of Grulke et al, with the pump operating at a variable rate, the gas pressure-driven motor being substituted with an electric motor, the motor operable at variable speeds, a control assembly with a switch to regulate the speed of the motor, a battery pack separate from the housing, and a flexible cable for supplying energy stored in the battery pack to the motor, as taught by Drews, as allowing the pump to operate at a variable rate or speed by an electric motor operating at variable speeds will allow the user the ability to vary the amount of fluid pressure applied to the patient at a given time based on the type of procedure being per-

formed, such as the infusion of an intravenous medium or to and fro washing of a cortex and/or nucleus of the eye in extracapsular cataract surgery (Abstract)(column 3, lines 56-66).

In regards to claims 40 and 41, in a modified irrigator of Grulke et al and Drews, Grulke et al does not teach a flexible cable. Drews teaches wherein:

> a. said cable includes a first conductor (circuit [152]) over which a first energization signal is available from said battery pack and a second conductor (circuit [154]) over which a second energization signal is available from said battery pack
>
> b. said control assembly is configured so that said switch member [36] can be selectively positioned to: connect neither of said cable conductors to said motor; connect the first said cable conductor to said motor; or connect the second said cable conductor to said motor (Figure 4)
>
> c. said control assembly is configured to sequentially move from the position in which neither said cable conductors are connected to said motor to the position in which said first cable conductor is connected to said motor and to the position in which the second said cable conductor is connected to said motor (Figure 4)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the modified irrigator of Grulke et al

and Drews, with a first conductor and a second conductor of the cable, as taught by Drews, as the speed of the motor and pump is proportional to the amount of pressure applied by the user to the switch to select a first or second conductor to provide for variable speed operation of the motor and pump (column 3, lines 56-62)(column 5, lines 1-17).

In regards to claim 42, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches that said pump is a reciprocating pump (Abstract).

In regards to claim 43, in a modified irrigator of Grulke et al and Drews, Grulke et al does not teach a battery pack. Drews teaches that an inlet tube (tube [28]) extends from the battery pack [14b] to the housing [12] (Figure 1]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the inlet tube, of the modified irrigator of Grulke et al and Drews, to extend from the battery pack to the housing, as taught by Drews, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70.*

In regards to claim 44, in a modified irrigator of Grulke et al and Drews, teaches that said tip assembly is constructed so that said outlet tube is disposed in said suction wand (Figure 9).

In regards to claim 45, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches wherein:

> a. a suction hose [100] having opposing ends is disposed in said housing (Figure 2)

b. said suction wand is connected to a first end of said suction hose (Figure 9)

c. said flexible suction tube is connected to a second end of said suction hose (Figure 2)

In regards to claim 46, Grulke et al teaches a medical irrigator (Figures 1-11) comprising:

a. a housing [11] having a front face (Figure 2)

b. a tip assembly [125] that extends from the front face of said housing, said tip assembly including an outlet tube [153] and a suction wand [144]

c. a pulse discharge pump [20] disposed in said housing, said pump having an inlet [193] and an outlet [192], the outlet opening into the front face of said housing so as to be in fluid communication with said tip assembly outlet tube

d. a flexible suction tube [124] that is in fluid communication with said tip assembly suction wand, said flexible suction tube extending away from said tip assembly

e. a single motor [204] disposed in said housing connected to said pump for actuating said pump

Grulke et al is silent about whether the pump operates at a variable rate, does not teach that the motor is a variable speed electric motor since the motor is a

gas pressure-driven motor (Abstract), is silent about whether the motor actuates the pump at variable rates, is silent about a battery pack separate from said housing that contains at least one battery, a flexible cable that extends from said battery pack to said housing, said flexible cable having at least one conductor over which an energization signal from said at least one battery is supplied, and a control assembly attached to said housing and connected between said at least one conductor and said motor for supplying a variable potential energization signal to said motor, said control assembly having a single switch member that is moveably attached to said housing that selectively makes/breaks a connection between said at least one conductor and said motor and that establishes the potential of the energization signal supplied to said motor. Drews teaches a medical irrigator (Figures 1-4) comprising a pump (pump [20]) that operates at a variable rate, a variable speed electric motor (motor [34]), wherein the motor actuates the pump at variable rates, a battery pack (battery power supply [14b]) separate from the housing, a flexible cable (electrical control cable [40]) extending from said battery pack to said housing, said flexible cable having at least one conductor (circuits [152][154]) over which an energization signal from said at least one battery is supplied, and a control assembly (control switch [36]) attached to said housing and connected between said at least one conductor and said motor for supplying a variable potential energization signal to said motor, said control assembly having a single switch member [36] that is moveably attached to said housing that selectively makes/breaks a connection between said at least one conductor and said motor and that establishes the potential of the energization signal supplied

to said motor. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the irrigator, of Grulke et al, with the pump operating at a variable rate, the gas pressure-driven motor being substituted with a variable speed electric motor, the motor actuates the pump at variable rates, a control assembly with a switch to regulate the speed of the motor, a battery pack separate from the housing, and a flexible cable with a conductor for supplying energy stored in the battery pack to the motor, as taught by Drews, as allowing the pump to operate at a variable rate or speed by an electric motor operating at variable speeds will allow the user the ability to vary the amount of fluid pressure applied to the patient at a given time based on the type of procedure being performed, such as the infusion of an intravenous medium or to and fro washing of a cortex and/or nucleus of the eye in extracapsular cataract surgery (Abstract)(column 3, lines 56-66).

In regards to claims 47 and 48, in a modified medical irrigator of Grulke et al and Drews, Grulke et al does not teach a cable. Drews teaches wherein:

> a. said cable has a first conductor (circuit [152]) over which a first energization signal is available from said at least one battery and a second conductor (circuit [154]) over which a second energization signal is available from said at least one battery
>
> b. said control assembly is configured so that said switch member [36] can be selectively positioned to: connect nei-

ther of said cable conductors to said motor; connect the first said cable conductor to said motor; or connect the second said cable conductor to said motor (Figure 4)

c. said control assembly has a first contact [36b] to which said first cable conductor is attached and a second contact [36b] to which said second cable conductor is attached and said contacts are statically mounted to said housing (Figure 4)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the modified irrigator of Grulke et al and Drews, with a first conductor and a second conductor of the cable and a first contact and a second contact, as taught by Drews, as the speed of the motor and pump is proportional to the amount of pressure applied by the user to the switch to select a first or second conductor to provide for variable speed operation of the motor and pump (column 3, lines 56-62)(column 5, lines 1-17).

In regards to claim 49, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches wherein:

a. the housing front end is formed with a fluid inlet opening in which said tip assembly suction wand is received (Figures 2 and 9)

b. a suction hose (suction hose [100]) is disposed in said housing and extends from the fluid inlet opening

c. said flexible suction tube is connected to said suction hose (Figure 2)

In regards to claim 50, in a modified irrigator of Grulke et al and Drews, Grulke et al teaches that said tip assembly is constructed so that said outlet tube is disposed in said suction wand (Figure 9).

Response to Arguments

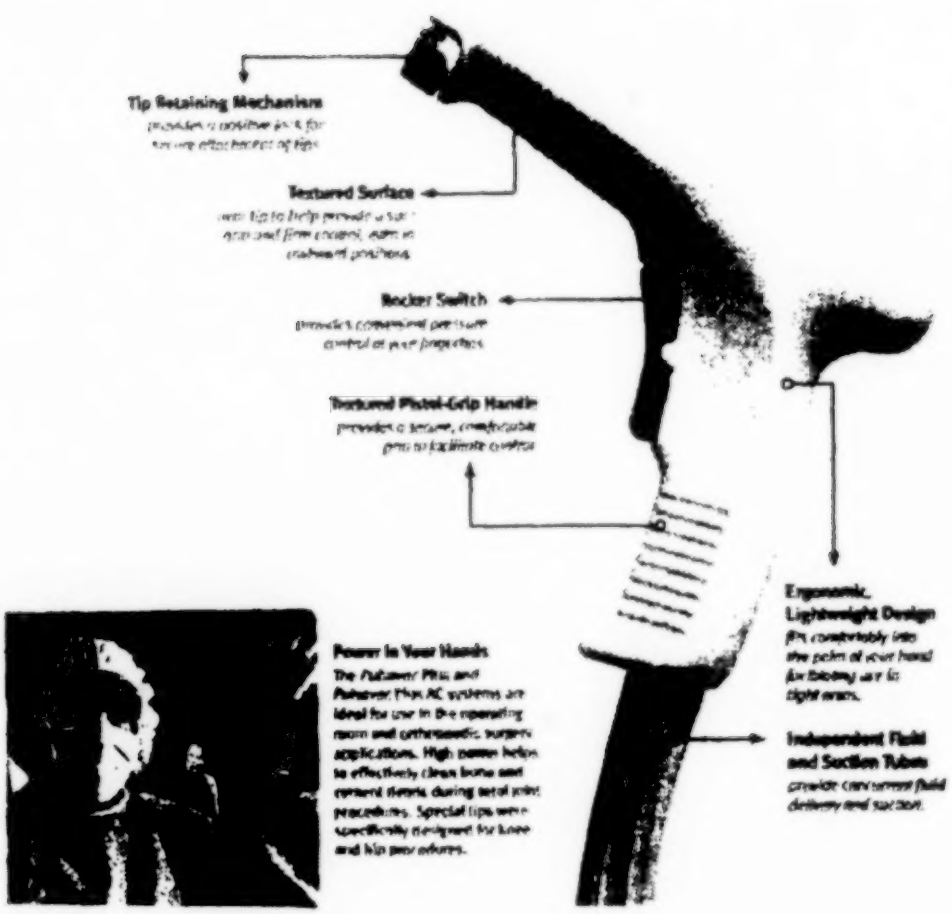
12. The rejection of claims 31-50 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7, 9, 20, 22-24, 38, 40, and 41 of US 7,144,383, in view of Olson (US 4,692,140), has been withdrawn, based on the acceptance of the terminal disclaimer of June 2, 2011. However, upon further consideration, a new ground(s) of rejection is made in view of Grulke et al and Drews.

* * * * *

PLAINTIFF'S
EXHIBIT
21
zimmer

Pulsavac® Plus Family

The *Pulsavac*® Plus, *Pulsavac* Plus LP and *Pulsavac* Plus AC wound debridement systems offer versatile solutions to wound irrigation, wound cleaning and therapy. Three models, featuring lightweight design and trigger-controlled pressure settings, offer a powerful cleaning action for bone or a gentle lavage for soft tissue. Concurrent suction and irrigation help to thoroughly remove debris and contaminants without flooding the field. The *Pulsavac* Plus and *Pulsavac* Plus AC are systems for use in orthopaedic and trauma cases. The *Pulsavac* Plus LP provides gentle lavage for soft tissue debridement.


Tip Retaining Mechanism
Textured Surface
Rocker Switch
Textured Pistol-Grip Handle
Ergonomic, Lightweight Design
Independent Fluid and Suction Tubes
Power in Your Hands

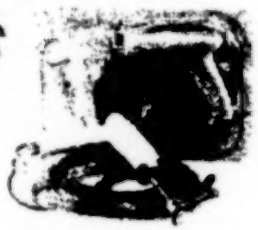
Debridement tips include the dust-cover splash shield, designed to minimize aerosolization and help control the dangers associated with transfluorant sprays.

The color coded dots to the left of the tips indicate system compatibility.

Combines convenience and power for smooth, efficient pulsative irrigation and debridement. The external battery pack hangs outside the sterile field, and the variety of tips and trigger-controlled pressure offers either powerful cleaning or gentle lavage. The primary application site is the operating room for orthopaedic surgery. Pulsavac Plus operates on eight AA batteries.

Storable AC Adapter
Eliminates the need for alkaline batteries, reducing the amount of waste.

Pulsavac Plus AC ▪
An environmentally-friendly option. The reusable AC Adapter Power Pack must be purchased separately. This system completely eliminates the need for alkaline batteries.



Pulsavac Plus LP ▪
This low pressure system delivers an adjustable, gentle lavage for wound cleaning and therapies and is an excellent alternative to traditional whirlpool therapy treatments. Primary application may occur in the OR, ER, wound care clinics, nursing homes or long-term care facilities. Therapy can be done in the patient's room or at the patient's home.

Low Pressure Debridement Tip Only

▪

Ordering Information

Prod. No.	Description
00-5150-420-00	Pulsavac Plus Component Kit
00-5150-475-00	Pulsavac Plus Fan Kit
00-5150-482-00	Pulsavac Plus Hip Kit
00-5150-495-00	Pulsavac Plus Shower Kit

Prod. No.	Description
00-5150-420-01	Pulsavac Plus Component Kit
00-5150-475-01	Pulsavac Plus Fan Kit
00-5150-482-01	Pulsavac Plus Hip Kit
00-5150-495-01	Pulsavac Plus Shower Kit

Prod. No.	Description
00-5150-958-00	Pulsavac Plus AC Power Supply (US)
00-5150-426-01	Pulsavac Plus AC Component Kit
00-5150-476-01	Pulsavac Plus AC Fan Spray Kit
00-5150-486-01	Pulsavac Plus AC Hip Kit
00-5150-496-01	Pulsavac Plus AC Shower Spray Kit

Prod. No.	Description
00-5150-920-00	Pulsavac Plus LP Component Kit
00-5150-975-00	Pulsavac Plus LP Fan Spray Kit
00-5150-995-00	Pulsavac Plus LP Shower Spray Kit

Prod. No	Description
00-5150-175-00	High Capacity Fan Spray w/Splash Shield, 12.7cm length
00-5150-176-00	High Capacity Fan Spray w/Filter
00-5150-195-00	High Capacity Shower Spray w/Splash Shield, 12.7cm length
00-5150-375-00	High Capacity Fan Spray w/out Splash Shield, 10cm length
00-5150-795-00	High Capacity Shower Spray w/out Splash Shield, 10cm length

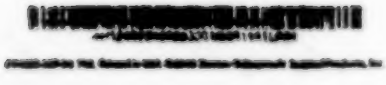
Prod. No.	Description
00-5150-155-00	High Capacity Single Stream Tip w/Splash Shield, 12.7cm length
00-5150-065-00	Large Fluid Orifice Tip w/Wide Single Stream, 7.3cm length

Prod. No.	Description
00-5150-181-00	High Capacity Bit Tip Four Orifices, 20.32cm x 1.27cm
00-5150-182-00	High Capacity Bit Tip w/Radial Spray, 22.86cm x .89cm
00-5150-183-00	High Capacity Bit Brush Tip w/Radial Spray, 22.86cm x .89cm x 1.52cm
00-5150-184-00	High Capacity Bit Hip Irrigation Tip, 7.5cm length
00-5150-185-00	High Capacity Bit Tip Four Orifices, 10.48cm x 1.27cm
00-5150-187-00	High Capacity Tibial Plateau Brush Tip, 7cm length

Prod. No.	Description
00-5150-145-00	High Capacity Adjustable Length Tip w/Splash Shield
00-5150-186-00	Flexible Tip, 18.5 inch length

Prod. No.	Description
00-5150-188-00	18cm Splash Shield
00-5150-189-00	23cm Splash Shield

zimmer



UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

STRYKER CORPORATION, STRYKER PUERTO RICO, LTD. and STRYKER SALES CORPORATION Plaintiffs and Counter-Defendants, v. ZIMMER INC. and ZIMMER SURGICAL, INC., Defendants and Counter-Plaintiffs.	)))))))Case No. 1:10-cv-1223))Hon. Robert J. Jonker)))))))

JOINT CLAIM CONSTRUCTION STATEMENT FOR DISPUTED CLAIM TERMS

Pursuant to the Court's Case Management Order, Plaintiffs, Stryker Corporation, Stryker Puerto Rico, Ltd., and Stryker Sales Corporation (collectively "Stryker"), and Defendants, Zimmer Inc. and Zimmer Surgical, Inc. ("Zimmer"), propose the following constructions for the disputed claim terms:

Claim Terms	Stryker's Proposed Claim Construction	Zimmer's Proposed Claim Construction
Handle	A portion of a device designed to be held by a hand or hands	Plain and ordinary meaning; no construction necessary
Adjacent	Close to or lying near	Plain and ordinary meaning; no construction necessary
Trigger	A lever pulled by a finger or fingers to activate a device or mechanism	Resilient lever designed to be pulled in a single direction
Lock Assembly	Components that work together to secure or fasten the tip to the hand piece	Subject to 35 U.S.C. §112 ¶6. Function: releasably securing the discharge tube and the suction tube to said body. Structure: a tip lock, a spring plate, a biasing bar, and a flange on a tip assembly.
Motor Operable at Varia-	A motor that can operate at more than	Motor with continuously variable speed

Claim Terms	Stryker's Proposed Claim Construction	Zimmer's Proposed Claim Construction
ble Speeds	one speed	
Variable Speed Electric Motor	An electric motor that can operate at more than one speed	Electric motor with continuously variable speed
Motor Operating at Variable Speeds	A motor that can operate at more than one speed	Motor with continuously varying speed
Control Assembly	Components that work together to energize the motor	Subject to 35 U.S.C. §112 ¶6. Function: • Claim 1: regulate the speed of said motor • Claim 20: control the speed of said motor and regulate the pumping rate of said pump • Claim 38: supplying a variable po-

Claim Terms	Stryker's Proposed Claim Construction	Zimmer's Proposed Claim Construction
		tential energization signal to said motor Structure: an L-shaped trigger member with an elongate trigger lever, a single switch contact support arm, a single conductive contact blade, two posts integral with the housing that are configured for electrical contacts to be mounted on them, two electrically-conductive, spring-like metal contacts mounted to said posts, and two electrically conductive contacts protruding rearwardly from the motor, one being a springy rectangular piece that is bent intermediate its ends in a dogleg

Claim Terms	Stryker's Proposed Claim Construction	Zimmer's Proposed Claim Construction
		fashion
Switch Assembly	Components that work together to make, break or change an electric circuit	Subject to 35 U.S.C. §112 ¶6. Function: selectively establishing a connection between at least one of said conductors and said motor Structure: a single conductive contact blade, two posts integral with the housing that are configured for electrical contacts to be mounted on them, two electrically-conductive, spring-like metal contacts mounted to said posts, and two electrically conductive contacts protruding rearwardly from the motor, one being a springy rectangular piece that is bent

Claim Terms	Stryker's Proposed Claim Construction	Zimmer's Proposed Claim Construction
		intermediate its ends in a dogleg fashion
Switch Member	A part for directing an electric current	Electrically conductive contact blade

Dated: October 21, 2011

Respectfully submitted,

/s/ David J. Gass
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Zimmer, Inc. and Zimmer Surgical, Inc.

Zimmer's Responses to Stryker's Infringement Contentions Regarding the '807 Patent

'807 Patent - Claim 45

45. An irrigating handpiece for receiving a tip assembly having a discharge tube and a suction tube, said irrigating handpiece including:

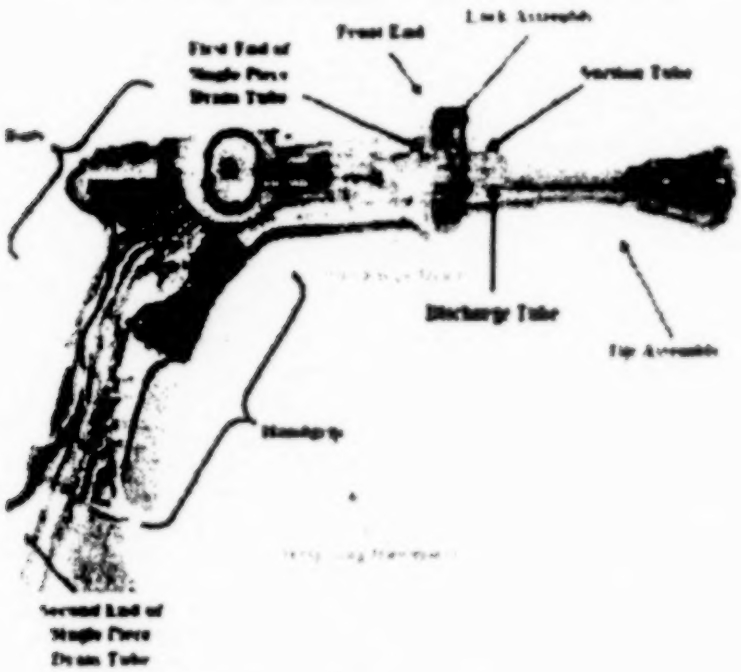
a body at least partially shaped to form a handgrip and a front end for receiving the discharge tube and the suction tube;

a lock assembly mounted to the front end of said body for releasably securing the discharge tube and the suction tube to said body;

a discharge head disposed in said body, said discharge head having an open end adjacent the front end of the body for receiving the discharge tube wherein, said discharge head receives irrigation fluid and discharges the irrigation fluid through the open end into the discharge tube; and

a single piece drain tube, said drain tube having a first end mounted in said body and a second end integral with the first end that extends outside of and away from said body, the first end of said drain tube being adjacent the front end of said body and being in fluid communication with the suction tube.

Stryker's Infringement Contentions



Zimmer's Response

Stryker's Initial Infringement Contentions do not specifically identify where each element of the asserted claim of the '807 patent is found within each Accused Instrumentality as required by LPR 2.2 (c) (N.D. Ill.). For example, it is unclear from Stryker's charts what element Stryker asserts is the single piece drain tube in the Zimmer product. Additionally, while Stryker accused Zimmer's Pulsavac Plus, Pulsavac Plus LP, and Pulsavac Plus AC ("the Accused Products") products of infringement, it appears that Stryker only provided charts relating to Zimmer's Pulsavac Plus product. Accordingly, Zimmer's responses below are based on Zimmer's current understanding of Stryker's infringement contentions. Additionally, Stryker does not allege any claim element in the '807 patent as present by equivalents. Therefore, Zimmer's non- infringement contentions are made with respect to literal infringement only. The parties

are in the early stages of discovery and Zimmer's investigation and analysis is ongoing. Zimmer reserves the right to supplement these responses.

Subject to the statements above, Zimmer states that the Accused Products do not embody each and every limitation of claim 45 of the '807 patent for at least the following reasons:

First, the Accused Products do not include a "single piece drain tube." The drain tube in the Accused Products is made of more than one piece.

Second, the Accused Products do not include a "lock assembly." The term "lock assembly," standing alone, does not connote sufficient structure to particularly point out and distinctly claim applicants' claimed invention. Accordingly, "lock assembly" should be construed as a means-plus-function claim limitation. The claimed function is "releasably securing the discharge tube and the suction tube to said body." Based on the specification of the '807 patent, the disclosed structure for performing this function is comprised of at least a plastic tip lock piece with a flat face plate, a spring plate that extends rearwardly from the face plate, a biasing bar in the handpiece that biases the spring plate, and a flange on the tip assembly that fits that interacts with the inner surface of the face plate.

(*See generally* '807 patent at 7:63-8:32, 10:17-28). The Accused Products do not have this structure or an equivalent, because the structure identified by Stryker on the Accused Products is manually operated by the user and therefore does not require any spring/biasing functionality.

Third, even if one assumed that the identified structure in the Accused Products is equivalent to the described disclosed structure, the Accused Products still do not contain a lock "assembly." The structure identified by Stryker on the Accused Products is a single piece, not an assembly of pieces.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

STRYKER CORPORATION, STRYKER PUERTO RICO, LTD., and STRYKER SALES CORPORATION,

Plaintiffs and Counter-Defendants,

v.

ZIMMER INC., and ZIMMER SURGICAL, INC.,

Defendants and Counter-Plaintiffs.

CASE NO. 1:10-cv-1223

HON. ROBERT J. JONKER

ORDER REGARDING STRYKER'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT

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[4]

Zimmer's final argument on Claim 2 of the 329 patent does identify a genuine factual issue for trial. Zimmer contends that the motor in its Pulsavac Plus device is not in the handle of the unit as required by Claim 2. (Ex. D, doc. # 158-4, at 2.) At claim construction, the Court defined "handle" to mean "a portion of a device that is designed to be held by a hand or

hands." (Order, doc. # 106, at 8-9.) The motor in the Pulsavac Plus is located in a nub, in roughly the same location as the hammer in a standard pistol. (*See* Ex. D, doc. # 158-4, at 2.) Whether this portion of the product was "designed to be held" is a question of fact on which reasonable jurors could disagree. Zimmer has produced evidence that would allow the jury to decide in its favor on this issue. The designed grips on the Pulsavac Plus, for example, do not extend to the nub that houses the motor, from which it may be inferred that the nub was not designed to be held. Zimmer has design witnesses that will testify in support of that inference. (*See* Def.'s Opp., doc. # 225, at 6.) As further support of its position, Zimmer can point to statements Stryker made in an effort to distinguish its own products from the prior art of the Mattchen patent. (*See id.* at 4-5.) On the other hand, there is also strong evidence that Stryker has presented to support a jury's conclusion that the nub area really does meet the "designed to be held" claim limitation. One of the Pulsavac Plus' lead designers is on record as demonstrating ways to hold the Pulsavac Plus so that the user's hand grips the nub on the device. (*See, e.g.*, Ex. S, doc. # 164, at 5 ("I mean, you can technically say [the nub's] a handle. You might be able to palm it.").) Furthermore, Zimmer's patent application for the Pulsavac Plus says that the "barrel *grip* encloses a motor and pump assembly," suggesting that the motor is part of the grip or, in other words, part of the handle. (*See* Ex. O, doc. # 160-5.) Accordingly, the Court cannot grant summary judgment on this aspect of Stryker's Motion under Claim 2 of the 329 patent.

* * * * *

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
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Defendants and Counter-Plaintiffs.

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HON. ROBERT J. JONKER

ORDER DENYING ZIMMER'S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF CLAIMS 45 AND 50-52 OF U.S. PATENT NO. 6,179,807 UNDER 35 U.S.C. § 102(B)

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[3]

II. ANALYSIS

Zimmer moves for summary judgment that claims 45, 50, 51, and 52 of Stryker's 807 patent are invalid as anticipated by the Var-A-Pulse. A patent claim is invalid as anticipated by prior art if each limitation in the patent is found in a single prior art reference. 35 U.S.C. § 102; *Apple Computer, Inc. v. Articulate Sys.*,

Inc., 234 F.3d 14, 20 (Fed. Cir. 2000). Consistent with this rule, a patent is invalid if it describes a device that was in public use or on sale in the United States more than a year before the date on which the patentee applied for the patent. 35 U.S.C. § 102(b). Summary judgment of invalidity is proper only "if no reasonable jury could find that the patent is not anticipated." *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001).

Stryker does not dispute that the Var-A-Pulse is prior art that was on sale in the United States more than a year before the 807 patent's priority date. Rather, it argues that the Var-A-Pulse did not include a "lock assembly," which is one of the limitations in claims 45, 50, 51, and 52 of the 807 patent. (Pl.'s Opp'n, doc. # 215.) The sole question presented by Zimmer's Motion, then, is whether a reasonable jury could find that the Var-A-Pulse did not include a "lock assembly," as the Court defined that term at claim construction. The Court concludes that the answer is yes.

Zimmer designed the Var-A-Pulse with a friction fit between the handpiece and tip. Zimmer can plausibly argue to a jury that a friction fit qualifies as "components that work together to secure or fasten the tip to the handpiece," but the record does not compel the jury to accept the argument. A reasonable jury could find, for example, that a fit based on friction does not involve a structure or assembly at all; or does not involve multiple components working together for that purpose; or even that the friction fit is not really about securing or fastening the tip to the handpiece. The record, for example, includes evidence that the Var-A-Pulse's "friction fit" mechanism often failed

to keep the device's tip in place during use, suggesting that some separate lock assembly was ultimately needed to accomplish that purpose. (Ex. D, doc. # 221-3, at 3.) Zimmer's own expert admits that the friction fit mechanism does not include any sort of structure, something normally required for an "assembly." (*See* Order, doc. # 106, at 13-14 ("A person of ordinary skill in the art would understand this claim term as describing a *structure* . . .").) And Stryker's technical expert insists that no one of ordinary skill in the art would consider the Var-A-Pulse devices to have a lock assembly. (*See, e.g.*, Ex. Q, doc. # 220-2, at 4-5.) Most importantly, the United States Patent Office knew of the Var-A-Pulse when it issued the 807 patent. (*See* Ex. E., doc. # 217-5, at 1.) The Patent Office's determination that the 807 patent did not infringe on the Var-A-Pulse is strong evidence that a reasonable juror could find for Stryker on this issue. *See Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004) ("This burden [of showing invalidity by clear and convincing evidence] is especially difficult when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution."). Such evidence precludes summary judgment here.

Zimmer objects that (1) that Stryker's expert has admitted that grooves in a handpiece can constitute components in a "lock assembly," and (2) that the instructions for the Var-A-Pulse explicitly directed users to "secure" the tip to the handpiece by means of the "friction fit" mechanism. (Def.'s Br. in Supp. of Mot., doc. # 171, at 12.) That evidence certainly bolsters Zimmer's position and will be of use to Zimmer at trial. But to prevail on a motion for summary judgment, Zimmer must do more than simply support

its position; it must demonstrate that the facts allow for no reasonable conclusion except the one it urges. The record does not rise to that level on this issue.

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UNITED STATES DISTRICT COURT
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Defendants.

CASE NO. 1:10-cv-1223

HON. ROBERT J. JONKER

JOINT PROPOSED JURY INSTRUCTIONS

[65] DISPUTED PROPOSED FINAL JURY INSTRUCTION NO. 26

Willful Infringement

In this case, Stryker argues both that Zimmer infringed and, further, that Zimmer infringed willfully. **The Court has already decided that Zimmer infringed claims 45, 50, 51 and 52 of the '807 patent, and claims 1, 2, 3, 8, 10, 11, 13, 17, 19, 20, 22, 24, 27, 38, 40 and 46 of the '383 patent. You must determine whether or not Zimmer's infringement of the '807 and '383 patents was willful. Additionally, if you have decided that Zimmer infringed claim 2 of the '329 patent, you must go on to determine whether or not Zimmer's in-**

fringement of the '329 patent was willful. [Stryker added; Zimmer objects] Willfulness requires you to determine by clear and convincing evidence that Zimmer acted recklessly. To prove that Zimmer acted recklessly, Stryker must prove two things by clear and convincing evidence: The first part of the test is objective: the patent holder must persuade you that Zimmer acted despite a high likelihood that Zimmer's actions infringed a valid patent. In making this determination, you may not consider Zimmer's state of mind. Legitimate or credible defenses to infringement, even if not ultimately successful, demonstrate a lack of recklessness. **Alternatively, if the defenses to infringement were not legitimate or credible then this first objective part of the test for willfulness has been met. [Stryker added and will send basis; Zimmer objects].** Only if you conclude that Zimmer's conduct was reckless do you need to consider the second part of the test. The second part of the test does depend on the state of mind of the Zimmer. The patent holder must persuade you that Zimmer actually knew or should have known that its actions constituted an unjustifiably high risk of infringement of a valid patent. To determine whether Zimmer had this state of mind, consider all facts which may include, but are not limited, to:

(1) Whether or not Zimmer acted in accordance with the standards of commerce for its industry;

(2) Whether or not Zimmer intentionally copied a product of Stryker's that is covered by the '329, '807, or '383 patents;

(3) Whether or not there is a reasonable basis to believe that Zimmer did not infringe or had a reasonable defense to infringement;

(4) Whether or not Zimmer made a good-faith effort to avoid infringing the '329, '807, and '383 patents, for example, whether Zimmer attempted to design around the '329, '807, and '383 patents; and

(5) Whether or not Zimmer tried to cover up its infringement.

(6) Whether Zimmer presented evidence that it obtained opinions of counsel to justify its infringing actions [Stryker added; Zimmer objects]

Authority: *Federal Circuit Bar Association Model Patent Jury Instructions* B.3.8 (February 2012); *see also* 3A FED. JURY PRAC.& INSTR. § 158:94

35 U.S.C. § 284; *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (standard for finding willfulness); *Knorr-Bremse v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc) (opinion of counsel defense); *Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1346 (Fed. Cir. 2001) (burden of proof for willfulness); *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1354 (Fed. Cir. 1999) (knowledge of the patent necessary to show willfulness); *Read Corp. v. Portec, Inc.*, 970 F.2d 816 (Fed. Cir. 1992) (identifying factors that may show willfulness); *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990) (history of Federal Circuit decisions on willfulness).

Stryker added the sentences stating "*The Court has already decided that Zimmer infringed claims 45, 50, 51 and 52 of the '807 patent, and claims 1, 2, 3, 8, 10, 11, 13, 17, 19, 20, 22, 24, 27, 38, 40 and 46 of the '383 patent. You must determine whether or not Zimmer's infringement of the '807 and '383 patents was willful. Additionally, if you have decided that Zimmer infringed claim 2 of the '329 patent, you must go on to determine whether or not Zimmer's infringement of the '329 patent was willful,*" in order to properly inform the jury that they must consider the issue of willfulness at least with respect to the asserted claims of the '807 and '383 patents given the Court's prior holding of infringement.

Stryker added the sentence stating "*Alternatively, if the defenses to infringement were not legitimate or credible then this first objective part of the test for willfulness has been met,*" pursuant to Federal Circuit law to balance the instruction that discusses "legitimate and credible" defenses. *See, e.g., Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, 682 F.3d 1003, 1005-1006 (Fed. Cir. 2012).

Stryker added the sentence stating "*(6) Whether Zimmer presented evidence that it obtained opinions of counsel to justify its infringing actions*" pursuant to Federal Circuit case law that holds that evidence relating to opinions of counsel – including the absence of such opinions – is relevant to willfulness and is properly presented to the jury for consideration. *See, e.g., Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 698 (Fed. Cir. 2008) (jury instruction stating that the jury may consider whether defendant sought a legal opinion as one factor in assessing whether, under the totality of the circumstances, any infringement

was willful "comports with our holding in *Knorr-Bremse*"); *Spectralytics, Inc. v. Cordis Corp.*, 2011 U.S. App. LEXIS 11981, at *27-28 (Fed. Cir. June 13, 2011) ("Precedent has also clarified that the failure to obtain an opinion of counsel or otherwise investigate the patent situation can be considered, in the totality of the circumstances."); *see also Retractable Techs. Inc. v. Becton, Dickinson and Co.*, 2009 WL 8725107, at *4 (E.D. Tex. Oct. 8, 2009) (Failure to produce an opinion of counsel at trial can be considered by the finder of fact as part of the "totality of circumstances" regarding willfulness. Thus, Plaintiffs should be permitted to introduce evidence or argument of this failure to produce an opinion of counsel at trial, although Plaintiffs cannot submit that any adverse inference should be drawn as to what the content of an opinion of counsel would have been.") (citing *Broadcom*); *DR Systems, Inc. v. Eastman Kodak Co.*, 2009 WL 3756765, at *11 (S.D. Cal. Nov. 9, 2009) ("While the accused infringer no longer has an affirmative obligation to obtain opinion of counsel, this fact may be considered in the totality of circumstances to assess whether any infringement was willful.") (citing *Broadcom*, 543 F.3d at 699); *Creative Internet Advertising Corp. v. Yahoo! Inc.*, 2009 WL 2382132, at **2, 5 (E.D. Tex. July 30, 2009) ("Defendant argues that its decision to not obtain an opinion of counsel regarding infringement is not determinative of this issue . . . . While this is correct, the lack of opinion of counsel is one factor of many that the jury could have taken into account in determining whether Defendant willfully infringed.) (citing *Seagate* and *Broadcom*); *In re Katz Interactive Call Processing Patent Litigation*, 2009 WL 3698470, at *3 (C.D. Cal. March 11, 2009) ("It is important to note that despite the lack of

adverse inference, the Federal Circuit still allows a jury to consider the absence of an opinion.") (citing *Broadcom*); *Energy Transportation Group, Inc. v. William Demant Holding*, 2008 WL 114861, at *1 (D. Del. 2008). *See also* Stryker's Opposition to Zimmer's Motion *in Limine* to Preclude Stryker from Referencing or Presenting Argument Relating to Zimmer's Decision not to Obtain an Opinion of Counsel or not to Waive Privilege and Disclose Opinions of Counsel.

ZIMMER OBJECTION:

Zimmer objects to Stryker's proposed language relating to the Court's prior finding of partial infringement on summary judgment as unnecessary in this instruction and highly prejudicial. If any reference to prior proceedings is deemed appropriate, it should be consistent with the Summary of Contention instructions as this issue is present there as well.

Zimmer also objects to Stryker's addition: "Alternatively, if the defenses to infringement were not legitimate or credible then this first objective part of the test for willfulness has been met." This is not in the model instructions, not legally sound, and highly prejudicial. *See, e.g., Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003 (Fed. Cir. 2012).

Zimmer objects to Stryker's addition: "(6) Whether Zimmer obtained opinions of counsel to justify its infringing actions." Zimmer is not relying on an advice of counsel defense to Stryker's willful infringement allegations. There is no legal obligation for Zimmer to obtain or waive privilege and produce opinions of counsel and, in the absence reliance on an opinion of

counsel, any reference to an alleged infringer's failure to obtain or waive privilege and produce opinions of counsel in the context of proving willful infringement is strictly prohibited under Federal Circuit law and highly prejudicial. *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007); *Knorr-Bremse v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc). Indeed, Federal Circuit Bar Association Model Instruction B.3.8 includes a factor for opinions of counsel for willful infringement specifically noting: "[***Give this instruction only if [alleged infringer] relies upon an opinion of counsel as a defense to an allegation of willful infringement***:" Here, Zimmer is raising no such defense.

UNITED STATES DISTRICT COURT
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ZIMMER INC., and ZIMMER SURGICAL, INC.,

Defendants.

CASE NO. 1:10-cv-1223

TRANSCRIPT OF JURY TRIAL
BEFORE THE HONORABLE
ROBERT J. JONKER
UNITED STATES DISTRICT JUDGE
GRAND RAPIDS, MICHIGAN

January 15-February 5, 2013

[23] THE COURT

Now, the product involved, the parties refer to it as -- I want to make sure I read this because -- it's called a pulsed lavage irrigation system. Now, I didn't really know what that meant. I've had the privilege of seeing some of the products -- and you will too, of course -- and the way I think of it as a layperson not at all familiar with the underlying design work is as a motorized squirt gun for surgeons. Okay? Now, that's not what the parties call it, and I don't want you to put too much on that, but I just want you to have a mental image of what we're talking about.

And you'll hear more about it, but, in essence, these are products that medical personnel can use in surgery or otherwise to apply water under pressure to a wound, or maybe to a bone that's getting prepared for a graft, or some kind of transplant or replacement, use it to clean that area and then suck out the water and debris that's a part of it, and to do it in a light-weight device that's held in the hand and that's disposable; that's used once and thrown away. Okay? That's the basic technology that we're talking about, and that's what the parties' claims are going to be about and the defenses. And that's probably all you need to know at this stage of the case.

* * * * *

[375] DIRECT EXAMINATION OF DAVID GRULKE

Q. Let's break that down just to the insides. What were the challenges you had in designing the electric motor and the gear train system to generate the pulsating flow?

A. The electric motor had a rotary motion that needed to be converted to a reciprocating motion in order to get the pulsating effect of the fluid.

Q. And why was that a challenge?

A. The power that the high-pressure tank gave us needed to be actually repeated with a very small motor and gear train assembly to transfer that motion to reciprocating and still allow the power of the unit to get a powerful enough pulse to clean bone.

Q. In the pulse lavage area had you ever seen anything like the electric motor and gear system that was developed at Stryker?

A. No, basically this is an all-encompassed unit that was never done before and pretty much revolutionized the industry at that time.

Q. So tell the jury, how do you feel about your work and the inventions for the SurgiLav Plus project?

A. I feel good. I think we accomplished what we needed to. We got great results from our customers, the healthcare workers. They said they loved it. It worked great. It was easy to use. It was something that they wanted.

Q. Okay. And before Stryker began developing the SurgiLav Plus project, were there any battery-operated pulse lavage systems in the marketplace?

A. No, not that I'm aware of.

* * * * *

"Stryker was the first company to capitalize on this with their disposable battery system, the SurgiLav Plus."

Do you agree with what?

A. Yes, sir.

Q. And the next sentence, "This product was able to take operating room business away from us over the past three years."

Do you see that?

A. Yes.

Q. That's referring to the Stryker SurgiLav Plus taking business away from Zimmer?

A. I believe it probably did, yes.

Q. Did it or was it probably?

A. It did.

Q. Could you highlight the sentence that says, "These battery-powered systems, with their quick setup and lack of capital equipment requirements, have made a major impact on the market."

Do you see that?

A. Yes, sir.

Q. That's talking about the pulsed lavage market, right?

A. Yes.

Q. Didn't those products revolutionize the market?

A. They were different. They were the first ones on the market like that.

Q. Didn't they change the entire market that got rid of the electric boxes, got rid of the pressure tanks, made those all old-school, obsolete, and if you didn't have a battery-operated product, you weren't going to be a player? Isn't that a fact?

A. I don't know if I can answer that for sure, sir. We continued to sell the Pulsavac machines and their products for quite a long time.

It certainly was different, and it certainly was more convenient for the surgeon.

Q. Are you selling any of the Pulsavac I, II, or III products?

A. No, sir.

Q. Okay. So you don't agree that the battery-operated systems that Stryker started revolutionized the market for pulsed lavage?

A. Perhaps it did. I don't -- revolutionize is a strong word, sir.

Q. Okay. Pioneered the market?

A. Pioneered, yes.

* * * * *

[476] DIRECT EXAMINATION OF WILLIAM DONIZETTI

Q. Okay. Now, we talked about H.M. Design, who they are, and their important part in developing the Pulsavac Plus. Did Zimmer demonstrate the Stryker SurgiLav Plus or InterPulse product to H.M. Design?

A. I believe we did, yes.

Q. Did Zimmer show H.M. Design the Stryker battery products because H.M. Design did not know anything about what they were designing or the market they were designing for?

A. I think we showed it to them to understand what we needed it to be to make our product better.

Q. I want to make sure you understood my question. Did Zimmer show H.M. Design the Stryker battery-operated products because, first, H.M. Design did not know anything about what they were designing?

A. Prior to -- prior to coming -- to us going to them, they had not been involved in pulsatile lavage.

Q. That wasn't my question. The question was did you show them the Stryker products because H.M Design did not know anything about what they were designing?

A. I don't believe that's why we showed it to them. We showed it to them because that was part of the development project.

Q. Okay. We'll get to that.

Did Zimmer show H.M. Design the Stryker battery-operated products because H.M. Design did not know anything about the market they were designing for?

A. That's true, they did not know the market. That's correct.

Q. Okay. So let's go back to the first one. Could you please bring up on the screen your deposition transcript testimony at 229, lines 8 to 16.

(Playing a portion of witness's video deposition)

Q. *(MR. VOGLER)* Did you give that answer to that question at your deposition?

A. Yes, I did.

Q. Do you now want to change your mind as to whether Zimmer showed H.M. Design the Stryker battery-operated products to H.M. -- do you want to change your mind as to whether Zimmer did show Stryker's products to H.M. Design because they didn't know anything about what they were designing?

A. I would say that's a fair statement, yes.

* * * * *

[485] DIRECT EXAMINATION OF WILLIAM DONIZETTI

Q. The question was did Zimmer take apart the Stryker SurgiLav Plus, take those parts and put it into a Zimmer prototype of the Pulsavac Plus?

A. I believe there was one item, yes.

Q. That's not benchmarking, is it?

A. That particular item was determined that it was patented, so we did not use it.

Q. Let me ask – taking somebody's part, putting – and you knew it was patented, the product was patented – and putting it into a prototype for your next product, is that benchmarking?

A. It's just a -- it's a – it was a valve.

Q. Was that benchmarking?

A. Yes.

Q. It was?

A. I'm not sure if it was benchmarking or not.

Q. That's right. Benchmarking is when you're testing performances between products, right?

A. You're trying to determine, yeah, what the product – how the product works.

Q. Yeah. Taking parts from your competitors to make your product, that wouldn't be benchmarking, would it?

A. I'm not sure.

Q. But Zimmer did take the valve system out of Stryker's SurgiLav Plus and put it into their prototype that was going to be used as a prototype for the Pulsavac Plus; do you agree with that?

A. Yes.

Q. Do you have the Stryker SurgiLav Plus up there?

A. Yes.

Q. Do you see that the tube and the wiring from the battery pack to the hand piece is connected together?

A. Yes.

Q. Would you call that coextruded?

A. I believe so, yes.

Q. Now, did Zimmer ever have a – and that's – let me back up. Now that's a wire, electrical wire, coextruded to a liquid tube, right?

A. Yes.

Q. Did Zimmer ever before seeing Stryker's SurgiLav Plus have an electrical wire coextruded to a tube for any pulsed lavage system?

A. No, sir.

Q. That was all new to Zimmer, wasn't it?

A. Yes.

Q. That's what Zimmer copied from Stryker, isn't it?

A. I guess you could say that.

Q. We will because we are.

Let me show you the paragraph on Section –

Call-out page 13.2. The third bullet point paragraph could you expand. Okay.

On that second – starting the second sentence it says, "It must be noted that Zimmer Patient Care does not have the capability to coextrude the wiring with the tubing as seen on competitive units; therefore, this type of design would have to be verified with the research of vendors and cost estimation of manufacturing and assembly."

Do you see that?

A. Yes.

Q. Zimmer hadn't done it before, but they certainly were going to copy Stryker on coextruding wires to tubing, right?

A. We hadn't done it before.

Q. And you copied.I mean, you stated just a second ago you copied.

A. Yes.

Q. Could you please pull up the '383 patent, Trial Exhibit 3. Could you go to claim 19. Okay.

Do you have an understanding that the Court has already found that Zimmer infringes claim 19 of the '383 patent?

A. I do now, yes.

Q. You do now.Okay. This claim talks about "Inlet line is a flexible hose that extends from outside said housing

into said housing. Said conductor assembly is attached to said hose so that at least a portion of said conductor assembly extends along said hose."

Now, isn't that patent talk for coextruding and combining electrical wire with a tube?

A. I believe it is.

* * * * *

[502] DIRECT EXAMINATION OF WILLIAM DONIZETTI

Q. And you said the Var-A-Pulse didn't have it, but does the Zimmer Pulsavac Plus product use a gear eccentric shaft which provides reciprocating motion for the pump?

A. Yes, it does.

Q. Did Zimmer copy from Stryker?

A. I don't know if we copied.

Q. Okay. Well, let me ask it this way: Where did you get the idea?

A. When we were in Indiana our product development group was out there, and we started developing the internal pumping mechanism for this, and one of our -- that's when we started using that, that eccentric shaft.

Q. And that was after you saw the Stryker SurgiLav Plus product, right?

A. It could have been. I don't know that for sure.

Q. Likely?

A. Maybe.

Q. Okay. I'll take "maybe."

And you opened up the SurgiLav Plus product, right?

A. Yes.

Q. And you saw that gear eccentric shaft in there, didn't you?

A. Yes.

Q. Did Zimmer -- I'm going to talk about another potential copying. Did Zimmer copy from Stryker the metal gear shaft to be used on the pump gear to solve heat problems?

A. I'm sorry, could you repeat that again?

Q. I can. Did Zimmer copy from Stryker the metal gear shaft used in the Pulsavac Plus on the pump gear to solve heat problems?

A. I know we have a metal shaft to go into the gear, yes.

Q. I'm not sure what the answer was. Did Zimmer copy that from Stryker?

A. I don't recall if we actually looked at it to say, "Let's use a metal pin like Stryker." I know we used a plastic one for a while and it didn't work, so we went to a metal one.

Q. Okay. Let's check out where you got the solution. Could you please pull up -- look in your book, please, to Exhibit 18. Are you there?

A. Yes. Sorry.

Q. What is Trial Exhibit 18?

A. These are meeting minutes from H.M. Design to Tim Donaldson on February 15th and 16th, 1999.

Q. And this document was provided to Zimmer?

A. Yes.

MR. VOGLER: Your Honor, I move admission of Plaintiffs' Exhibit 18.

MR. HAYES: No objection, Your Honor.

THE COURT: It's admitted without objection.

Q. (*MR. VOGLER*) Can we then pull up on the screen the second page of Exhibit 18. And expand and highlight the top bullet point.

And we're talking about the metal gear shaft in the previous questions, and here is what it says in a Zimmer document: "A metal gear shaft will need to be used on the pump gear because of the heat buildup from the high number of RPMs in the motor. This was a problem that the competition Stryker had and was resolved with a metal shaft."

Do you see that?

A. Yes, sir.

Q. This is one of the documents that talks about the design of the Pulsavac Plus, isn't it?

A. Yes.

Q. Now, would you agree with me Zimmer was able to find the solution to the heating problem by copying Stryker?

A. I know we used a plastic one, it didn't work, so we had to make it better, and we went to a metal one.

Q. It didn't work because it overheated, right?

A. That's correct.

Q. And the solution was Stryker's metal shaft, right?

A. The solution was metal.

* * * * *

[622] DIRECT EXAMINATION OF NEIL SHEEHAN

Q. How does copying, if at all, affect an analysis of willful infringement?

A. It is a supporting piece of analysis. So if copying is also found, that supports the -- my -- well, as you'll see, supports my view that this infringement was and still is willful.

Q. What is your opinion about whether Zimmer copied Stryker's commercial products?

A. Yeah, they have. There have already been admissions in this courtroom about that by Zimmer wit-

nesses. And I concur, or they concur with me, that there has been copying. And I will show you.

MR. VOGLER: Can we please place up on the screen Exhibit 260.

And, for the record, these are quotes from Exhibit 23 which is in evidence.

Q. (*MR. VOGLER*) Mr. Sheehan, what is the purpose of Exhibit 260?

A. Okay. I think you may have seen this before. This is an internal document called a business case. And as a Zimmer witness testified accurately, this is where you put together the documentation as to why you want to spend "X" amount of dollars to do "X" -- to do a project. It gets sent around to all the departments, especially the money department, to justify the expenditure. So in connection with that, a lot of things are said in this kind of document to convince the bosses, "Hey, we have to spend this dough."

Q. And how does it relate to willful infringement?

A. Well, let's take a look at the highlighted portions. It acknowledges Stryker was the first company to capitalize on this. And they are talking about the disposable self-contained unit with their battery system, the SurgiLav Plus. Remember, that's the first Stryker product. That's the white one.

"This product was able to take operating room business away from us over the past three years." So this goes to motivation. They are getting their clock cleaned a bit here, and so they are highly motivated to try to come up with something.

Secondly, in one section, page 10 -- that's what this number over here means, by the way. This .10 means it's on page 10. Stryker's strength is that it's a market innovator. Pioneer.

Q. Okay. Can we please put up on the screen the next slide, Exhibit 261, which also contains information from Trial Exhibit 23.

How does the information on Exhibit 261 relate to willful infringement?

A. Well, this is from the same document on different pages, and it confirms -- once again, this goes to motivation. Zimmer Patient Care Division attempted to compete in the disposable battery system market. That's shorthand for having the batteries separate and having a self-contained handpiece like the SurgiLav Plus. And Zimmer responded with the Var-A-Pulse in March of '96 three years after the release of the SurgiLav Plus.

This is a product that was rushed to market and has been dogged by reliability and functionality issues. So their first response was a dog, and so now "We've got to do something about that."

They acknowledge to themselves it was a poorly designed product with little thought given to ergonomics or user needs. It's already been explained, and you can see it here, that it's ergonomically deficient, that that's how the hand interacts with the device and their heavy eight batteries on the six-speed bottom part. They acknowledge that the Var-A-Pulse, their first shot, had poor flow rate. The tips fell off.

Additionally, they highlight again that Zimmer's market share has eroded due to poor performance and product-quality issues. They are kind of beating a dead horse at this point. They have got their problems.

"Their current design is not only forcing us out of the disposable market but may also eliminate us from being a player in the lavage market in the future." So we're talking up against the wall. And that would be the motivation. Goes to motivation to copy.

Q. Can we please place up the next exhibit, 262, which contains information from Trial Exhibit 14 which is in evidence.

What -- how does the information of Exhibit 262 relate to willful infringement?

A. This continues to tie into the evidence. There's -- motivation is still in here. This -- oh, this document, by the way, is a proposal from H.M. Design, the folks that they decided to hire, notwithstanding their lack of experience, to do -- to do this project. And their objective is to recapture the lost sales and improve product liability. Sales force confidence is obviously having -- is at a low, and they are acknowledging that performance leadership is coming from Stryker.

And the item that you need -- the first item -- there are multiple bullet points, but this is the first one: Sample of Competitive Units. And it is my understanding and I believe the testimony of Mr. May is that that was a Stryker unit that they had, the Surgi-Lav Plus.

Q. How does the information from Exhibit 14 relate to willful infringement?

A. Oh. It shows the intention to go ahead and copy the SurgiLav Plus. To copy Stryker's products.

Q. Could we please place up the next exhibit, 263, which comes from Trial Exhibit 13 which is in evidence.

How does the information on Exhibit 263 relate to willful infringement?

A. Well, this is more evidence of copying. This is a -- shortly after that proposal by H.M. Design they have a meeting, and in attendance are a couple of folks from Zimmer, both of whom you've met, one live and one on videotape. And they are acknowledging that they do not have the capability to coextrude the wiring with the tubing as seen on competitive units. And this ground has already been covered, so I'll try to be as brief as possible. They are just saying "We can't do this."

And what we all know is the SurgiLav Plus was the first device in this market to do that. They obviously recognized the value of it, and so they are going to have to look into having somebody figure out how to do that since they can't do it with in-house.

And finally, this bullet point down here goes to that issue, this odd issue that a prototype was supplied to H.M. Design that had in it a dual-valve configuration, and now you're talking about the pump. This is the configuration that allows the pump to push water out and then to reload some water, push some more water

out, reload. So you need two valves to do that. And the prototype actually had a Stryker part in it. That's not benchmarking. That's odd.

Q. And on the first box where it talks about basically coextruding electric wire to the tubing, what do you recall about -- from the testimony of Mr. Donizetti as to copying or not copying that feature?

A. I believe he acknowledged that they copied it from Stryker.

Q. Could we turn to the next slide, 264, please.

A. And I would add that that is a limitation in some of the infringed claims of the '383.

Q. Yeah, let's clear that. What do you mean by it's a limitation in one of the infringed claims?

A. In the '383, which you haven't had the need to see but it's in this same family, same specification, but those claims -- and there are many more claims in that one; there were 16 infringed claims versus four infringed claims in the '807, and we're dealing with just the one in the '329 -- there are what are called dependent claims. And I don't think that's been discussed, so I'll take a moment.

An independent claim is a claim that has everything described in it. A dependent claim says everything that's in the claim above but also with the additional limitation that I only mean brown whistles or red potatoes, something like that. It's a further narrowing, but it is a separate invention, so it will say "The device as in Claim 1" -- so it says "Claim 2, the

device as in Claim 1 wherein," and then it adds another limitation.

So this attaching of the wire to the tubing occurs in those dependent claims. So there's your lesson for that.

Q. I'm actually going to go to Exhibit 265.

Sorry. I changed my mind. 264 first. I apologize.

Mr. Sheehan, how does the information on Exhibit 264, which comes from Trial Exhibit 17, relate to willful infringement?

A. Well, it sets up the -- oh. First, this is a -- meeting minutes. There were -- there was a meeting. This was written on the 11th, so there was some meeting prior to that. All these folks from Zimmer were there. And it reads "The operation of the punk --" "Punk." Sorry. "-- the pump mechanism was reviewed. It was noted that the Stryker -- that Stryker utilizes a combination duckbill valve and umbrella valve. This application has been patented. The design team will utilize a duckbill valve and an umbrella valve in the new design."

Now, at first blush -- and you saw Mr. May seem awfully confused by it, and it is confusing. It looks like it says "This is patented, but we're going to go do it anyway."

I think, in fairness, the combination duckbill/umbrella valve is a very clever invention by Stryker, and also manufactured by Vernay. You've heard that company mentioned. I've worked with them for decades. Terrific company in Yellow

Springs, Ohio. And it's a combination duckbill where it has an umbrella valve tied to it. Trust me, it's cool.

So it would appear here that the design team decided to -- it's hard to tell, but maybe they used -- they were going to say "We'll use a duckbill and an umbrella" or -- it's not clear.

Now, we saw evidence when a counsel for -- not counsel -- a witness showed you their accused products and showed that they didn't have a duckbill, that they were using two umbrella valves. So in the end, that precise thing was not particularly copied, but the functioning of those valves is -- they are the same.

Q. And how does Zimmer looking at Stryker's system and its functioning relate to Zimmer's copying?

A. Well, it tells me that the reference, the paradigm, the model for the artist -- you know, the artist painting and has a model over here, you paint the model -- was the SurgiLav Plus. It was not that horrible Var-A-Pulse that didn't work very well that everybody said was terrible, et cetera. Had batteries in a circle like a Russian spacecraft and six speeds. It just -- that wasn't the reference to it while they were working on the Pulsavac Plus. The inspiration, the source of much of the -- what became the Pulsavac Plus was the SurgiLav. Were Stryker products.

Q. Okay. Can we go to the next slide, slide 265, please. This is information from Trial Exhibit 18.

Mr. Sheehan, how does the information on slide 265 relate to willful infringement?

A. Certainly. This is shortly thereafter, I guess it's the next month, it says February, and they are discussing meetings that occurred on the 15th and 16th. And some more Zimmer folks are there. And here is this item, you've seen it before, that there was a -- "a metal gear shift will have to be used on the pump gear." And the pump gear spins around pretty fast. And you would get heat buildup from the high number of RPMs -- revolutions per minute -- from the motor. This was a problem that the competition Stryker had and was resolved with a metal shaft.

Now, the first question is: How did they know Stryker had that problem? Are they going through dumpsters? unless they had been taking apart Stryker units, which is not in and of itself inappropriate, but they have obviously been keeping track of this. Stryker solved it by using a metal shaft. And you might say, "Oh, well, that doesn't sound like much of a breakthrough." Well, it is, because the plastic shaft you would have gotten for free. It would have been part of that molded -- you saw half of a housing. You could have molded that shaft coming right out and gotten it at the same time you molded the housing parts. And cost is huge. Cost is -- you know this -- cost is huge in the medical device industry. So -- and I believe finally Mr. Donizetti admitted that Zimmer copied Stryker's metal shaft.

Second bullet point: "There will be no designs with batteries in the handle." Okay, that's out. It tells you Var-A-Pulse was not their reference. Var-A-Pulse had eight batteries all around and six speeds. That is what the -- oh, then it says, "This information was derived from customer input from the academy show, and this is what the competition is currently doing --"

well, it says "during," but it's supposed to be "doing" -- engineers don't often use the best English -- "with their design."

So they are just saying "Stryker has the batteries outside of the unit. We need to do that too."

And by the way, those are also claim limitations in the '383.

Finally, the last bullet point, box point, "Need a form model to help understand the concept of the shape and multiple hand positioning." Var-A-Pulse could be only held one way. The SurgiLav Plus, which is that very elegant white object, device, could be held all along it. Beautiful.

They want to have multiple hand positioning, so they copied that aspect.

But wait, there are some concerns that the design may look too much like the competition. Now, here somebody among the group is sort of saying, "Whoa. Maybe we better dial back the similarities." So for me, that's continued proof, evidence of Zimmer's copying.

Q. Mr. Sheehan, were you here when the deposition testimony of -- Mr. Daniel Olson, one of the designers of the Zimmer's Var-A-Pulse, testified?

A. Yeah. He was the nice fellow with the beard. Nice fellow.

Q. Could we call up a portion of his -- a very short portion of his testimony.

Okay. Mr. Sheehan, how does the information or the testimony of Mr. Olson relate to willful infringement?

A. Well, we can just read along the highlighted area. He said this. You saw him not live but on the screen, on TV. "We were trying to -- we didn't want to go into as much gear-driven as we could, we wanted to avoid that because the gears just -- they are a pain."

And he's right in the sense it takes a lot of good engineering to develop this gear-train system.

And then a second answer, he acknowledges "We would probably -- we would be probably copying somebody if we had gone with the gear drives." That "somebody" would have been Stryker.

Q. And how does that relate to willful infringement?

A. Well, as you'll see shortly, the identical gear system in the SurgiLav Plus and in the InterPulse show up in the Pulsavac Plus.

* * * * *

[642] DIRECT EXAMINATION OF NEIL SHEEHAN

My question to you, just generally, what is your opinion regarding the reasonableness of Zimmer's invalidity defenses?

A. I found those too to be -- those as well to be unreasonable.

Q. And what's just a general overview basis for that?

A. Certainly. As you saw in the opening presentation by Mr. Vogler, the Patent Office in granting all of these patents, all of the claims in all of the patents, looked at essentially the same prior art that is now being presented by Zimmer with a higher burden of proof required, which is clear and convincing evidence. What you may not know, that in the Patent Office the burden of proof is preponderance of the evidence. But that's inside the Patent Office when they issue the patent. To overturn a patent, you need that higher standard of clear and convincing evidence. And furthermore, if the art has been before the Patent Office before or is cumulative on it, then that burden is particularly hard to meet.

So the bulk of the prior art that Zimmer is relying upon was either before the Patent Office or cumulative, meaning the same information or the same type of product. And that is another reason why it's an unreasonable defense. You're just bringing out stuff that the Patent Office already looked at and looked at carefully.

These file histories are very thick. This is not about some new piece of prior art that they found in Germany or somewhere like that. This is just -- it's just unreasonable to think that the same prior art now with a higher -- doubly higher standard is going to carry the day. It's just not reasonable.

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[703] CROSS-EXAMINATION OF NEIL SHEEHAN

Q. And you may have said this, I don't remember, but Zimmer's Var-A-Pulse is prior art to the '807 patent, correct?

A. Correct.

Q. So in claim 45, you disagree -- I'm sorry -- you agree that the Var-A-Pulse satisfies all of the limitations except the lock assembly limitation?

A. Correct.

Q. On claims 50 through 52 -- I don't know -- just to be clear, because I don't know if you went all the way down and looked at those -- you agree that the Var-A-Pulse has those characteristics as well, correct?

A. You're correct. I didn't look down, but let me just make sure. Correct.

Q. So out of all of the limitations of the asserted four claims of the '807 patent --

A. Uh-huh.

Q. -- you agree that they are all present in Zimmer's own prior art Var-A-Pulse product --

A. Correct.

Q. -- except the lock assembly?

A. Right. This being the independent claim, and these dependent claims since they depend from the inde-

pendent claim, this limitation is also built into these three claims, and so that's true for all of them, yes. "This limitation" being a lock assembly mounted to the front end.

Q. So if -- I'll speak up. If I were to -- if I put Var-A-Pulse -- if I put Var-A-Pulse at the top and then wanted to indicate the elements that the Var-A-Pulse has, I could check everything but lock assembly, correct?

A. Correct.

Q. Which I think I've done accurately close up. Correct?

A. Yes.

Q. Now, you understand that Zimmer asserts that the Var-A-Pulse also satisfies the lock assembly limitation, correct?

A. That's my understanding, yes.

* * * * *

[758] REDIRECT EXAMINATION OF NEIL SHEEHAN

Q. And what is your opinion as to whether it is reasonable for Zimmer to rely upon that combination of Grulke and Drews 2 for its patent invalidity argument?

A. It's unreasonable. It is not reasonable.

Q. Okay. Let's break that down. First of all, what's the burden the Patent Office has for rejecting claims?

A. Interestingly, inside the Patent Office the burden is different from what we face here. Here Zimmer must show by clear and convincing evidence the higher standard. In the Patent Office it's the lower preponderance of the evidence. So the Patent Office has a lower standard to meet when they do office actions.

Q. So, I mean, what does --

MR. HALES: If I may, I want to lodge the objection to Mr. Sheehan, like he was at the end of the prior week, talking about the law as if he's an expert on law.

THE COURT: All right. He, of course, can only talk about his expert opinion, and to the extent anything he says about the law differs from what I say about the law, the jury has to follow what I say about the law. Okay?

Go ahead, Mr. Vogler.

MR. VOGLER: Okay.

Q. (BY MR. VOGLER) So how does that make a difference in the different burdens between the Patent Office and what Zimmer has to prove here in this case?

A. Well, the preponderance of the evidence is more likely than not. You know, 50/50. 51. Just past the 50 yard line. Clear and convincing is just -- it's just a much higher standard to reach.

Q. Okay. Now let's -- the '383 patent is one of Stryker's patents in this case, right?

A. Yes, sir.

Q. Okay. What is your understanding as to whether the Patent Office already considered the Grulke patent and the Drews 2 patent when it allowed the claims of the '383 patent?

A. It had -- the Patent Office had already seen and considered Grulke and Drews 2.

Q. And what is your understanding of the effect that the Patent Office already considered those when they granted the '383 patent?

A. My understanding of that is that reaching that already high clear-and-convincing standard is especially difficult given that the Patent Office already looked at those.

Q. Could you please put on the screen Exhibit 3 from the '383 patent at call-out page 3.24. There you go.

Mr. Sheehan, this is from the '383 patent?

A. Right.

Q. Right from it, right?

A. Yes, it is.

Q. Okay. What's your understanding of what Stryker was telling the Patent Office in its background of the invention?

A. Well, in the specification submitted to the Patent Office -- and this goes back to the very first time it was submitted, the earliest application back in '93 --

here the inventors, and one of whom is Mr. Grulke himself, the title on the patent '383 is Arnett, et al. -- et al. means "and others," et alii, from the Latin -- here the inventors are actually pointing out to the Patent Office how Grulke and that the Grulke 5,046 -- sorry, I'm pointing with my finger -- the Grulke 5,046,486, and that's the patent we're calling Grulke, they are explaining why their invention here in the '383, their claims differ from this older prior art in the highlighted section. And I'll read this just to make sure there's a record. "As compared to the above-mentioned prior device --" meaning the Grulke air-actuated device, the nitrogen -- "a pulse irrigation handpiece embodying the present invention is producible at a lower cost, produces sharper liquid pulse transients, particularly the pulse-off transient, requires no connection to any operating power source, for example, compressed air or to an external pump, and instead is self-contained, requires only external connection to a liquid irrigation source, for example, conventional irrigation liquid bag, provides better suction when suction is required, is more compact, and is conveniently shaped to be held either as a pistol or a wand." By the handle or barrel.

So what you have here is the teaching away. This is called teaching away when the inventors in their patent application and their specification teach away from using an older piece of prior art in a validity analysis.

Q. Okay. Could I please pull up call-out page 3.5. Okay. Obviously, we're on cue.

In the '383 patent under the references cited there's the 4,817,599 Drews patent?

A. Yes.

Q. That's the Drews 2 patent, right, we're talking about?

A. That's my recollection of the number.

Q. And what does this tell you that's in the '383 patent?

A. That, in fact -- this is just the proof that they considered -- that Drews 2 was before the Patent Office, along with Grulke of course.

Q. Okay.

A. And numbers of others.

Q. Okay. Could you pull up Trial Exhibit 288.

Mr. Sheehan, what are you trying to show here with Exhibit 288?

A. Well, this sort of emphasizes what Mr. Grulke and his co-inventors said to the Patent Office regarding the '383 patent. The original Grulke which was considered by the Patent Office is a pressurized gas-powered device. In other words, has the large nitrogen tank that's hooked up here. Here is the P for pressure. It goes up into this motor pump combo. I'll come back to that. That's important. And here is the exhaust. And then you have your liquid going in and your suction coming out here.

There's no electric motor. There is absolutely no electric motor. This has nothing to do with electricity. The power source it requires connection to is, of

course, this large tank of pressurized typically nitrogen.

So there's nothing in here that asks or would be reasonably -- reasonable to do in terms of adding anything electric to it. And one of the extra reasons is that this is not a motor and a separate pump. This is a motor/pump combo. Inside of that is a piston that goes up and down, and underneath it is the nitrogen, and above it is the liquid. It's one thing. So you can't say, "Oh, I'll separate the gas source and put some electric motor down here." It wouldn't work.

So that's the purpose of that slide.

Q. Could we turn to the next slide, 290, please.

Mr. Sheehan, what are you trying to show on Exhibit 290?

A. Well, we've already established that even starting with Grulke is unreasonable. Now, to further combine that with Drews 2, Drews 2 is an eye-washing system. Drews 2 is used in a delicate eye surgery. So to the extent there is water flow, it's dainty and it's sort of like (making noise). Very dainty. And so it's very low pressure. It's not suitable for cleaning bone or anything like that. Also, there's no suction. Remember, suction is part of this whole '383 invention. This just delivers fluid here. Oh. And it's not disposable. Grulke, famously, says "I'm disposable." So this is not a disposable system.

And it also is operated or partly controlled by this foot pedal, which would be in -- you know, in the sterile field.

And finally, this is a rotary peristaltic motor, the kind of motors I work with in the dialysis world. And the purpose of that motor is gentleness. The reason you use rotary peristaltic pumps in dialysis is because you don't want to damage the red blood cells. That's called hemolysis. You break a red blood cell, it doesn't carry oxygen. And there have been deaths associated with poor pumping in dialysis clinics.

So the purpose of using this kind of pump here is for the gentle swish-swish that would occur. And this switch, by the way, is not an on/off switch. This switch is a choice-of-mode switch. And you can either have it in a direct irrigation flow or you can switch it back to what's called to and fro. In fact, the name of that patent is the to-and-fro washing system.

Q. Okay. What's your -- what do you conclude about the validity of the '383 patent claims in view of your analysis of Grulke and Drews 2?

A. Well, they are valid and not obvious.

Q. What is your understanding of the role of objective evidence in the analysis of whether a patent claim is valid?

A. The role of objective evidence is by my lights very important. It's different from the let's call it subjective evidence of looking at two pieces of prior art. And in this case Grulke and Drews 2, which I think it's clear that they don't render the claims obvious, but there's more reasons.

Q. Could you please put on the board Trial Exhibit 291.

MR. HALES: Your Honor, I object. I think we're beyond the scope of my cross-examination on this material.

THE COURT: Well, I think the cross-examination certainly touched on what we've heard so far, the issues involving the handle, the issues involving the '504 application, and more generally the question of reasonableness of positions on obviousness. So I think it's within the scope of proper redirect. Go ahead.

MR. VOGLER: Thank you, Your Honor.

Q. (BY MR. VOGLER) Mr. Sheehan, what is your understanding as to whether the examiner in the '504 patent application had the objective evidence showing nonobviousness of Stryker's inventions?

A. The examiner would not have had that information. That's essentially never the case. The examiner is simply looking at the pieces of prior art. Examiners, in my experience, never see this.

Q. What is your opinion of why that would make a difference?

A. Oh, it makes a huge difference, because to the extent anybody were inclined to think that two pieces of prior art that might look like, well, maybe you could combine them, and, well, maybe you could get the invention, these five here would tend to push those pieces of prior art away.

If somebody says, "Oh, well, that's obvious," well, if it were so obvious, then why would there be praise in the industry? Why would there be copying, et cetera? That's the setup, if you will, for these ques-

tions which are -- have been established as objective indicia or sometimes called secondary considerations.

Q. Now, what real-world evidence are you aware of in this case that would support that Stryker's patents are not obvious?

A. Sure. Well, we can just --

Q. Just briefly.

A. -- walk down these very quickly.

Praise in the industry. Well, we heard that happen a little over a week ago, Mr. Donizetti allowing how Stryker's products were pioneering. If not revolutionary, they were pioneering. Copying, I believe --

Q. Let me back up on that pioneering.

A. Oh, sure.

Q. Now, you've been involved with a lot of patent cases, right?

A. Yes, sir.

Q. And how often have those cases involved pioneer inventions like the type in this case?

A. Very rarely.

Q. Okay. Continue with the evidence.

A. Copying, I think, we've already -- I believe I've shown you enough to indicate that copying has gone on. There's been a lot of evidence about that.

Long-felt and unmet need. Those large boxes which are no longer gracing the well area here, that was the standard. And even the Grulke device with its large nitrogen tank, that was the standard. So -- and that was the standard for more than a decade. So was there a long-felt and unmet need for the '383 invention? And for that matter the '329 or the '807 invention? Absolutely.

Now, evidence of nonobviousness additional is whether the patent has been licensed by others. And in this case, in this situation it's my understanding that Davol has taken a license from Stryker.

And finally commercial success. The question is, "Hey, if this were so obvious, how come they sold so many? Why didn't somebody else do it?" And I'm pretty sure my numbers are correct, but to date the devices sold by Stryker, Davol, and Zimmer have been more than a billion dollars. I think maybe 1 1/4 billion maybe. But I know more than a billion dollars since 1993. So that's what I would call commercial success.

Q. Okay. Now, Zimmer's attorney asked you some questions about the abandonment of the '504 application. Do you recall that?

A. I do.

Q. What's your opinion on that?

A. Well, "abandoning" is kind of a cold word. It's hardly that.

When one files a continuation, which happens all the time, it's one of the many options you have during the prosecution of a patent, you're required to aban-

don the other one. So you don't abandon it first and then do a continuation, you do a continuation, and then by law the Patent Office says you must abandon the prior one. You can't have two sets of the same claims being looked at by the Patent Office at the same time.

Q. In your book there's an Exhibit 38. Could you turn to that?

A. I have it.

Q. What is Exhibit 38?

A. Exhibit 38 is the continuation application, what is known as the '540.

MR. VOGLER: Your Honor, I move for admission of Trial Exhibit 38.

THE COURT: Any objection?

MR. HALES: No objection, Your Honor.

THE COURT: Okay. All right. It's admitted without objection.

Q. (BY MR. VOGLER) Mr. Sheehan, what's the date of the continuation of Exhibit 38?

A. That would be March 8th, 2012.

Q. And how does that date relate to the date of abandonment of the '504 patent?

A. I believe the date of abandonment is about four days later. So this occurred in the appropriate order.

Q. Okay. Now, what is your understanding as to whether Stryker abandoned any of the claims of the patent application '504 and in the continuation?

A. In fact, Stryker didn't abandon any of the claims. All we saw earlier, or the week before last, was this one claim that counsel for Zimmer put up. In fact, there were 20, 20 claims within the '540 application that are at this very time still under the consideration of the PTO.

* * * * *

[1386] DIRECT EXAMINATION OF CRAIG MILROY

Q. I want to switch gears for a minute and take a look at Exhibit QF, which is the '504 application. We've seen this a number of times.

Can you turn in your binder to Exhibit QF, please, Mr. Milroy.

A. QF. Yes.

Q. Did you consider this in forming your opinions in this case?

A. Yes, I did.

Q. Ken, can we have page 13 of Exhibit QF.

I would like to highlight paragraph 11 to the end.

Mr. Milroy, what do we see here?

A. These are comments by the Patent Office. Stryker has applied for a patent which we call the '504 applica-

tion. They have applied for that, and the Patent Office has said, "No, we reject claims 31 through 50 based on Grulke and Drews."

Q. And this is the board we've seen before, correct, Mr. Milroy?

A. Yes, we have.

Q. So what do we see on this board?

A. On the left we have the claims, claim 1 of the '383 patent and all of its elements.

On the right-hand side we see claim application, '504 application with claim 31. You can see that all of those elements on the left are listed on the right with one additional element.

Q. And what did the Patent Office say about the claim elements on the right?

A. The Patent Office dismissed all of them.

Q. In view --

A. Rejected all of them in favor of information they found from Grulke and Drews II.

Q. And is that the same Grulke and Drews II prior inventions we've been talking about today?

A. Yes, it is.

Q. So what effect, if any, does this Patent Office's rejection of the '504 application have on your opinions

with respect to whether or not claims 1, 2, 3, and 8 of the '383 patent are invalid as obvious?

A. Well, I looked at it and thought it was valid and it – it was invalid and obvious. And the Patent Office looking at something very similar said the exact same thing.

Q. Just one follow-up. What is your understanding of Stryker's response to the Patent Office's rejection of the '504 application claims?

MR. VOGLER: Could you repeat that?

Q. (BY MR. HAYES) What is your understanding of Stryker's response to the Patent Office's rejection of the '504 application claims?

A. They abandoned it.

Q. Did they say anything in response to the Patent Office?

A. No, they didn't respond at all.

* * * * *

[1402] DIRECT EXAMINATION OF CRAIG MILROY

Q. And what steps have you performed -- we've talked about them, but can you generally highlight the steps you performed in performing your obviousness analysis in this case?

A. Sure. One of the things you look at is you look at the function of something. Is it functioning the same way? Is it known, first of all? Is it something that's

out there that they would know about? Does it function the same way? And do you get the same result? So if you look at those, then you can combine those as being obvious.

Q. Are you actually trying to combine, for example, the motor, little motor in Drews II into -- that exact motor into the -- for example, the Grulke device?

A. That's a good question. No, we're not taking -- when I compare Drews II to Grulke, I'm not saying you take the motor out of this device and put it in this device. That obviously wouldn't work. You would have to make some changes. But the question is would it have been obvious to someone who did this kind of work? Sure, I can put that in there without issues.

* * * * *

[1434] CROSS-EXAMINATION OF CRAIG MILROY

Q. You've heard of the word -- phrase "pioneering invention"?

A. Yes.

Q. What is your understanding of "pioneering invention"?

A. I think a pioneering invention could be something that is really different. The pioneers found new territory in the United States. That's, I think, where the term comes from. So pioneering invention is something that is, you know, plowing new ground.

Q. And that's something -- a pioneering invention is a pretty big deal in the industry, isn't it?

A. Yes.

Q. And is it fair to say that pioneering invention normally changes the course of what people do in an industry?

A. Yes, I'd say that's valid.

Q. Would you agree that a pioneering invention in technology is normally considered a major leap in that technology?

A. I would agree with that, yes.

Q. Is it fair to say that pioneering inventions are never obvious?

A. Yes, I agree they are out of the ordinary often.

* * * * *

[1444] CROSS-EXAMINATION OF CRAIG MILROY

Now, on the bottom left we see that you changed that. Before, you said the handle was from below the trigger to here, and now you've raised it up to the top of the trigger. Do you see that?

A. I do see that, yes.

Q. So you've had three positions on what a handle is in this case, correct?

A. Well, they are in three different areas of my report, and they may be in two different reports. So if you put it in context, then I'm trying to show where this device would be held by the hands.

Q. You know, you keep -- I don't want to argue with you, but you say "in context." This is the context. This is from your report where you show where the handle is, right?

A. It's one of the areas in my report where I show where -- where portions are to be held by the hand or hands or what I consider to be the handle of the object.

Q. Okay. Do you know what a declaration is filed by experts in patent cases?

A. I believe I do.

Q. You filed one in this case, didn't you?

A. Yes.

Q. And they are filed under oath to tell the truth?

A. Yes.

Q. I'm going to show you what you filed with the Court to tell the truth on Exhibit 298. Is that your signature?

A. Yes, it is.

Q. December 5th, 2011?

A. Yes, it is.

Q. And this is what you stated as the truth: "I understand that Stryker has proposed that 'handle' means any portion of a device designed to be held by a hand or hands. I disagree with Stryker's proposed construction of 'handle' --" and here is the important part -- "because it would render the barrel, the handle, and the entire housing of the claimed irrigation handpiece a handle." Do you see that?

A. Yes, I do.

Q. That's the truth, isn't it?

A. Well, it's the truth that I understood it at the time.

Q. Well, you can't tell the truth one day and then change your mind, can you?

A. It depends on the input I'm getting and the things I look at. Opinions change, and this is my expert opinion, and I attest that this is my opinion at this time.

Q. Hasn't this just proven Stryker's case of infringement? And I'll tell you why. Because a minute ago I got you to agree that the entire housing of the Pulsavac Plus includes where the motor is. Right?

A. I did say that the motor is in the barrel, yes.

* * * * *

[1452] CROSS-EXAMINATION OF CRAIG MILROY

Q. And let's talk about the clear and convincing standard. What does that mean to you?

A. That means that you have to show that those prior -- the prior art, the prior inventions existed and show that they existed and show that they clearly existed before the date of the granted patent.

Q. That's not what clear and convincing standard means, does it?

A. Well, I'm not a lawyer.

Q. Weren't you here when the Court explained it?

A. Yes, I was.

Q. Okay. That's a good point. You're up here giving opinions of why you think the patent is invalid and you don't even know what clear and convincing standard you have to meet, do you?

A. No, I do. What I look at based on my experience --

Q. Then explain to us what is your understanding of a clear and convincing standard.

A. From a legal point of view or from my expert point of view?

Q. From your understanding.

A. My understanding of it is that you have to show that a person of ordinary skills in the art at that time would have had -- I have to show evidence that a person at that time would have had the resources available to them and it would have been obvious to show that these things existed.

Q. Is that your answer?

A. Yes.

Q. Okay. Mr. Milroy, what is your understanding of using hindsight in an analysis of patent validity?

A. You're not allowed to use hindsight.

Q. And what is hindsight?

A. Hindsight is looking back and saying, "Well, based on what I know now, that wouldn't be valid." And so you can't -- you have to put yourself back in the time, back in that time, not knowing what people know now but what they knew then, and, again, a person of ordinary skills in the art, what that person knew at that time.

* * * * *

[1686] REBUTTAL DIRECT EXAMINATION OF NEIL SHEEHAN

Now, Zimmer has suggested that -- the question was Zimmer has suggested that it could not have copied Stryker's patents in suit because the patents issued after Zimmer completed its development work. What's your reaction to that?

A. Well, it's true that the patent issued later, but the product was on the market. And the question of copying goes to copying the commercial embodiment. So the product itself was on the market. That's what was copied. In fact, both of them, the SurgiLav Plus and the InterPulse.

Q. Of course, do you understand that on Exhibit 240 the original SurgiLav Plus patent application was filed in 1993?

A. Correct.

Q. And when was the first patent issued from the SurgiLav Plus application?

A. Yeah, this is really interesting. This is the very first patent that publishes on November 28th, 1995. And if you will remember, the specification -- that is all those words, all those pictures, all those descriptions in the patent specification -- they are all identical. So as soon as this published, Zimmer was on notice of what the specification was for every one of these patents, including the '329 and the '383, two of the patents in suit.

Q. And did Zimmer's product development for the Pulsavac Plus happen after 1995?

A. Oh, yes.

* * * * *

[1869] THE COURT

In this case Stryker argues both that Zimmer infringed and further that Zimmer infringed willfully. You must determine whether any infringement by Zimmer of valid claims under the patents at issue was willful.

Willfulness focuses on whether Zimmer acted recklessly. The burden of proof is on Stryker to prove by clear and convincing evidence that Zimmer acted

recklessly.

Stryker -- let me start this again. All right. So the burden is on Stryker to prove by clear and convincing evidence that Zimmer acted recklessly. Stryker must prove two things by clear and convincing evidence to prevail on this issue. First, from an objective point of view, that Zimmer acted despite a high likelihood that Zimmer's actions infringed a valid patent; second, that Zimmer actually knew or should have known this.

In making the first determination, you may not consider Zimmer's state of mind, rather consider objective factors such as whether Zimmer raised legitimate or credible defenses to infringement, even if they were not ultimately successful, or whether defenses appeared contrived and insubstantial. These objective factors should be the focus of your first inquiry.

If you decide that Zimmer acted despite an objectively high likelihood of infringement of a valid patent, you will need to consider the second part of the test. The second part of the test does depend on the state of mind of Zimmer.

Stryker must persuade you by clear and convincing evidence that Zimmer actually knew or should have known that its actions constituted an unjustifiably high risk of infringement of a valid patent. To determine whether Zimmer had this state of mind, consider all facts which may include but are not limited to whether Zimmer acted in accordance with the standards of commerce for its industry, whether Zimmer intentionally copied a product of Stryker's that's covered by the '329, '807, or '383 patents, whether there

is a reasonable basis to believe that Zimmer did not infringe or had a reasonable defense to infringement, whether Zimmer made a good-faith effort to avoid infringing the '329, '807, and '383 patents, for example, whether Zimmer attempted to design around the '329, '807, and '383 patents, whether Zimmer tried to cover up its infringement, whether Zimmer presented evidence that it obtained opinions of counsel to justify its infringing actions, and whether Zimmer's state of mind was affected by any of Stryker's conduct in the marketplace or the timing of Stryker's filing of this lawsuit.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

STRYKER CORPORATION, STRYKER PUERTO RICO, LTD., and STRYKER SALES CORPORATION Plaintiffs and Counter-Defendants, v. ZIMMER INC., and ZIMMER SURGICAL, INC., Defendants and Counter-Plaintiffs.	Case No. 1:10-cv-1223 Hon. Robert J. Jonker U.S. District Judge

JOINT STIPULATION REGARDING DEPOSITION TESTIMONY PRESENTED AT TRIAL

Plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., and Stryker Sales Corporation ("Stryker") and Defendants Zimmer Inc. and Zimmer Surgical, Inc. ("Zimmer") hereby stipulate that the following deposition testimony was presented to the jury at the trial in this matter:[1]

---

[1] With regard to the videotaped deposition testimony of William Donizetti and Joan Fishel (Exs. C, F

1. Excerpts from the Videotaped Deposition of Daniel Henry Olson Played on January 16, 2013 at Dkt. No. 357, page 351, line 22 (attached as Exhibit A)

Page 6, lines 5-7
Page 10, lines 2-9
Page 22, lines 11-20
Page 67, lines 4-14
Page 67, line 24 – Page 68, line 10
Page 71, line 17 – Page 73, line 16
Page 74, lines 7-8
Page 74, lines 11-25
Page 75, line 2

* * * * *

[71] Daniel H. Olson

Q. Uh-huh. Where in general did you look, then, for -- when you said you got the concept for the rotary linear pump from the field, what other types of products were you looking at?

A. Some of them, you know, all kinds of pumps, really. We were trying to -- we didn't want to go into as much gear driven as we could. We want to avoid that because the gears just -- they're a pain. Plus we –

---

and H), the parties stipulate that the identified deposition testimony was presented to the jury; however, the parties disagree as to whether that testimony was offered for impeachment purposes or as substantive evidence. Zimmer alleges that the testimony is available only as impeachment evidence and not as substantive evidence; Stryker alleges that the testimony is available as substantive evidence.

Q. But the --

A. -- we would be probably copying somebody if we had gone with the gear drives.

* * * * *

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

STRYKER CORPORATION, STRYKER PUERTO RICO, LTD., and STRYKER SALES CORPORATION,	:	CASE NO. 1:10-cv-1223
Plaintiffs,	:	HON. ROBERT J. JONKER
v.	:	
ZIMMER, INC., and ZIMMER SURGICAL, INC.,	:	
Defendants.	:	

VERDICT FORM

We, the jury, unanimously answer the questions submitted as follows:

PART I: INFRINGEMENT

Burden of Proof	The burden is on Stryker to prove Infringement by a preponderance of the evidence

Key Idea	Does the "accused device" have every element of the particular patent claim at issue, either literally, or by the "doctrine of equivalents"?

1. Did Stryker carry its burden of proving by a preponderance of the evidence that Zimmer literally infringed Claim 2 of the '329 Patent?

__X__ Yes _____ No

2. Did Stryker carry its burden of proving by a preponderance of the evidence that Zimmer infringed Claim 2 of the '329 Patent by the Doctrine of Equivalents?

__X__ Yes _____ No

PART II: INVALIDITY

Burden of Proof	The burden is on Zimmer to prove Invalidity by clear and convincing evidence
Key Idea	Does "prior art" make the particular patent claim "anticipated" (a single reference), or "obvious" (multiple references in the context of secondary factors) to someone "skilled in the art"?

For each of the following Claims, answer where requested whether Zimmer has carried it burden of proving by clear and convincing evidence that the Claim is invalid as "Anticipated" or "Obvious" (or both) under the instructions I have given you for each doctrine.

		ANTICIPATED?		OBVIOUS?	
1.	Claim 2 of the '329 Patent	____Yes	X No	____Yes	X No
2.	Claim 45 of the '807 Patent	____Yes	X No	____Yes	X No
3.	Claim 50 of the '807 Patent	____Yes	X No	____Yes	X No
4.	Claim 51 of the '807 Patent	____Yes	X No	____Yes	X No
5.	Claim 52 of the '807 Patent	____Yes	X No	____Yes	X No
6.	Claim 1 of the '383 Patent			____Yes	X No
7.	Claim 2 of the '383 Patent			____Yes	X No
8.	Claim 3 of the '383 Patent			____Yes	X No
9.	Claim 8 of the '383 Patent			____Yes	X No
10.	Claim 10 of the '383 Patent			____Yes	X No
11.	Claim 11 of the '383 Patent			____Yes	X No
12.	Claim 13 of the '383 Patent			____Yes	X No

		OBVIOUS?	
13.	Claim 17 of the '383 Patent	____ Yes	X No
14.	Claim 19 of the '383 Patent	____ Yes	X No
15	Claim 20 of the '383 Patent	____ Yes	X No
16.	Claim 22 of the '383 Patent	____ Yes	X No
17.	Claim 24 of the '383 Patent	____ Yes	X No
18.	Claim 27 of the '383 Patent	____ Yes	X No
19.	Claim 38 of the '383 Patent	____ Yes	X No
20.	Claim 40 of the '383 Patent	____ Yes	X No
21.	Claim 46 of the '383 Patent	____ Yes	X No

PART III: REMEDY

SUBPART A: MONEY DAMAGES

Burden of Proof	The burden is on Stryker to prove the amount of Money Damages by a preponderance of the evidence.
Key Idea	Assuming Zimmer infringed valid patent claims, what amount of money would put Stryker in the position it would have occupied without the infringement?

1. Did Stryker carry its burden of proving by a preponderance of the evidence that Stryker is entitled

to recover any lost profits because of Zimmer's sales of infringing products?

__X__ Yes _____ No

If you answered "Yes," enter the dollar amount you find Stryker has proved by a preponderance of the evidence it is entitled to recover as lost profits:

$ 70 MILLION

2. What is the reasonable royalty rate (in percent) that you find Stryker has proven by a preponderance of the evidence should apply to any covered sales of infringing products by Zimmer, assuming validity and infringement of all three patents in suit?

25 % (double initial percentage of Duel license as we felt 32.2% was too high)

a. Do you find that the reasonable royalty rate would be any different if fewer than all three of the patents in suit are valid and infringed?

_____ Yes __X__ No

b. If "no," skip to the next question. If "yes," what is the reasonable royalty that you find Stryker has established by a preponderance of the evidence should apply for each of the patents in suit individually?

_____ % assuming that only the '329 patent is valid and infringed

_____ % assuming that only the '807 patent is valid and infringed

_____ % assuming that only the '383 patent is valid and infringed

3. What is the dollar amount of sales by Zimmer to which you find Stryker has proven by a preponderance of the evidence the reasonable royalty rate should apply, assuming validity and infringement of all three patents in suit?

$ 254,823,154

a. Do you find that the dollar amount of sales to which the reasonable royalty rate should apply would be any different if fewer than all three of the patents in suit are valid and infringed?

X Yes _____ No

b. If "no," skip to the next question. If "yes," what is the dollar amount of sales by Zimmer to which you find Stryker has established by a preponderance of the evidence the reasonable royalty rate should apply for each of the patents in suit individually?

$ 254,823,154 assuming that only the '329 patent is valid and infringed

$ 254,823,154 assuming that only the '807 patent is valid and infringed

$ 163,647,429.50 assuming that only the '383 patent is valid and infringed

PART III: REMEDY

SUBPART B: MARKING

Burden of Proof	The burden is on Stryker to prove proper Marking by a preponderance of the evidence.
Key Idea	Did Stryker appropriately mark "substantially all" of its own products with the applicable patent numbers; and, if so, by what date?

1. Has Stryker met its burden of proving by a preponderance of the evidence that it acted reasonably in choosing the mark product labels, rather than the plastic product itself?

__X__ Yes _____ No

2. Has Stryker met is burden of proving by a preponderance of the evidence that it marked substantially all of its products with the applicable patent number?

a. For the '329 Patent?

__X__ Yes _____ No

If yes, by what date? Dec 10, 2004

b. For the '807 Patent?

__X__ Yes _____ No

If yes, by what date? Dec 10, 2004

c. For the '383 Patent?

__X__ Yes _____ No

If yes, by what date? March 16, 2007

PART III: REMEDY

SUBPART C: WILLFULNESS

Burden of Proof	The burden is on Stryker to prove Willfulness by clear and convincing evidence.
Key Idea	Was there an objectively "high likelihood" of liability; and, if so, did Zimmer know or should Zimmer have known it?

Has Stryker met its burden of proving by clear and convincing evidence that Zimmer acted willfully in infringing any valid claims under the applicable patent?

a. For the '329 Patent?

__X__ Yes _____ No

b. For the '807 Patent?

__X__ Yes _____ No

c. For the '383 Patent?

__X__ Yes _____ No

SIGNATURE BLOCK

We, the jury, unanimously return this verdict form as our verdict in the case:

Date: February 5, 2013 — Jury Foreperson

Date: 2/05/13

Date: 2/5/13

Date: 2/5/13

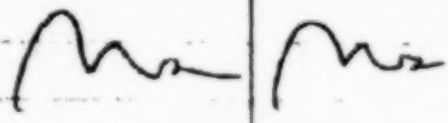
Date: 2-5-13

Date: 2/05/13

Date: 2-5-13

Date: 2-5-13

can we see all of the physical devices? claim charts as well



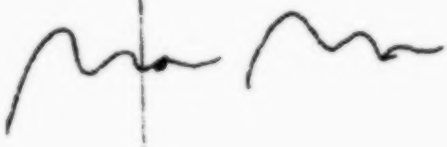
3:30
2-4-13
#1.

Would it be possible to have the large claim charts in the jury room to present and view all at once as a group?

2:4-13
4:40

(#2)

We've no where near a conclusion. See you tomorrow



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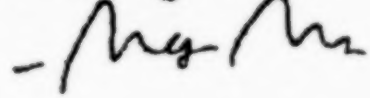
(#3)

Is there a copy of Mrs Lawton's Full report that we can reference?

Also, [redacted] would it be possible to watch the "Rick May" deposition video again?



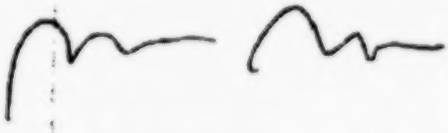
#3 12:[illegible]-5-13

Are we allowed to come up wit
our own figures for either
lost profits amounts or reasonal
royalty, i.e., come to a compro

If we find one claim of severe
obvious, does that make +
#4 whole patent invalid?

12:30 #4 2 5-13

We have come to a conclusion and filled out the verdict form.



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#5

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

STRYKER CORPORATION, STRYKER PUERTO RICO, LTD., and STRYKER SALES CORPORATION,

Plaintiffs and Counter-Defendants,

v.

ZIMMER INC., and ZIMMER SURGICAL, INC.,

Defendants and Counter-Plaintiffs.

CASE NO. 1:10-cv-1223

HON. ROBERT J. JONKER

FINAL JUDGMENT AND PERMANENT INJUNCTION

Based on the prior rulings of the Court and the verdict of the jury, and after considering the proposed forms of judgment submitted by the parties, IT IS ORDERED, ADJUDGED, DECLARED and DECREED that the Plaintiffs Stryker Corporation, Stryker Puerto Rico, Ltd., and Stryker Sales Corporation have judgment against Defendants Zimmer Inc. and Zimmer Surgical, Inc., as follows:

1. That Defendants Zimmer, Inc. and Zimmer Surgical, Inc. have infringed, literally and under the

doctrine of equivalents, claim 2 of Stryker U.S. Patent No. 6,022,329, claims 45, 50, 51, and 52 of Stryker U.S. Patent No. 6,179,807, and claims 1, 2, 3, 8, 10, 11, 13, 17, 19, 20, 22, 24, 27, 38, 40, and 46 of Stryker U.S. Patent No. 7,144,383;

2. That Defendants' infringement of the asserted claims of Stryker U.S. Patent Nos. 6,022,329, 6,179,807, and 7,144,383 was willful;

3. That this case is exceptional pursuant to 35 U.S.C. § 285;

4. That enhanced damages are appropriate pursuant to 35 U.S.C. § 284;

5. That the counterclaims and defenses raised by Zimmer are dismissed with prejudice, and that normal principles of issue and claim preclusion govern any unasserted counterclaims and defenses;

6. That Stryker is entitled to and awarded lost profits damages in the amount of $70 million;

7. That Stryker is entitled to and awarded supplemental damages in the amount of $2,351,257.66 for the period December 1, 2012 to February 28, 2013;

8. That Stryker is entitled to and awarded supplemental damages in the amount of $3,757,635 for the period March 1, 2013 to June 30, 2013;

9. That Stryker is entitled to and awarded treble damages on its lost profits award as well as its supplemental damages awards;

10.That Stryker is entitled to and awarded reasonable attorneys' fees in an amount to be determined following the entry of final judgment;

11.That Stryker is entitled to and awarded prejudgment interest of $11,167,670.50 on the jury award and the supplemental damages incurred from December 1, 2012 to February 28, 2013, prejudgment interest of $1,094,982.78 on the damages incurred from March 1, 2013 to June 30, 2013, and prejudgment interest calculated at a rate of 3.83%, compounded monthly, on Stryker's reasonable attorneys' fees and on any damages for the period July 1, 2013 to the entry of final judgment;

12.That Stryker is entitled to and awarded postjudgment interest in an amount to be calculated in accordance with the statute.

IT IS FURTHER ORDERED, ADJUDGED, DECLARED and DECREED that Defendants Zimmer Inc. and Zimmer Surgical, Inc. are hereby permanently enjoined from the manufacture, use, importation, sale, or offer for sale within the United States of the pulsed lavage products found to infringe claims 45, 50, 51, and 52 of U.S. Patent No. 6,179,807, and products no more than colorably different therefrom.

Dated: September 5, 2013

/s/ Robert J. Jonker
ROBERT J. JONKER
UNITED STATES
DISTRICT JUDGE